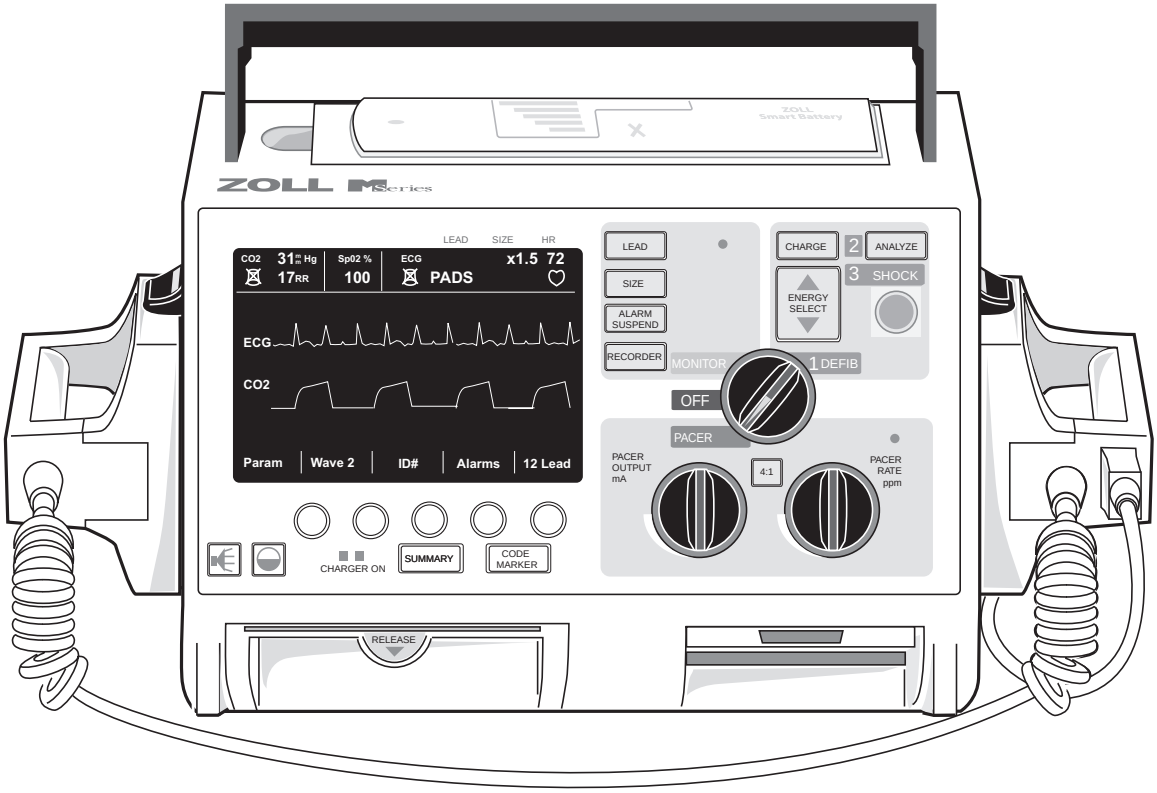
ZOLL

M Series

OPERATOR'S GUIDE



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If more than three years have elapsed since this date, contact ZOLL Medical Corporation to determine if additional product information updates are available.

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SECTION 1
GENERAL INFORMATION

NOTE: Your M Series may or may not contain all the features listed in this manual, depending on your particular configuration.

Product Description

The ZOLL **M Series** products combine a defibrillator, ECG display, advanced monitoring capabilities, and Noninvasive Transcutaneous Pacing (NTP) with communication, data printing and recording capabilities in a single lightweight portable instrument. The unit has been designed for all resuscitation situations and its small, compact, lightweight design makes it ideal for accompanying patients during transport. The product is powered by AC or DC mains and an easily replaced battery pack that is quickly recharged in the device when it is connected to AC or DC mains. In addition, the unit's batteries may be recharged and tested using ZOLL PowerCharger systems designed for standard interchangeable ZOLL battery packs.

The product is designed for use in both the hospital and the rugged EMS environment. All of its ruggedized features add to its durability in hospital applications. The device is a versatile automated external defibrillator with or without manual capabilities and may be configured to operate in manual, advisory or semi-automated modes. Semi-automated versions of the device have a distinctive front panel with a single "**ON**" position. Conventional hospital style devices, which can be configured for manual, advisory or semi-automated operation, have a standardized ZOLL operator interface. When operating in the manual configuration the device operates as a conventional defibrillator where the device's charging and discharging is fully controlled by the operator. In advisory and semi-automatic modes, some features of the device are automated and a sophisticated detection algorithm is used to identify ventricular fibrillation and determine the appropriateness of defibrillator shock delivery. Units may be configured to automatically charge, analyze, recharge, and prompt the operator to "PRESS SHOCK", depending on local protocols. The unit is switched from the semi-automated mode to manual mode for ACLS use by pressing the appropriate soft key on the front panel.

Information regarding the unit's operation, patient ECG, and other physiological waveforms are displayed on a large 5.66 inch diagonal display which provides high contrast and visibility under virtually all lighting conditions. Operating and warning messages are displayed on the monitor and the unit can also be configured with voice prompts to alert the user to unit status. Self-diagnostic tests are performed when the instrument is turned on and the unit is periodically tested during operation.

A sophisticated data collection system, an optional internal summary report feature with printer, and PCMCIA cards are available for this unit. A PCMCIA card can be installed in the unit to record ECG and virtually all device data when the device is turned on. In addition, voice data from any incident around this device can also be recorded. The data stored on the PCMCIA card can be reviewed and archived on a properly equipped personal computer using ZOLL Data Control software.

An annotating strip chart recorder can be included to provide immediate documentation as well as summary report functions about patient care and treatment during use.

Some **M Series** products are intended for use in the semiautomatic mode by first responders and emergency medical technicians certified by an appropriate federal, state or local government authority. Some **M Series** products are intended for use in manual mode by personnel certified by appropriate federal, state or local authority to provide advanced life support care.

Some **M Series** products are intended for use in the pre-hospital emergency medical care setting, indoors and outdoors, including first response vehicles, fire vehicles, basic and advanced level ambulances as well as by both Basic Life Support (BLS) and Advanced Cardiac Life Support (ACLS) staff in hospitals under protocol control.

How to Use This Manual

The **M Series** Operator's Guide provides information operators need for the safe and effective use and care of the **M Series** products. It is important that all persons using this device read and understand all the information contained within.

This manual is organized for manual mode operators, advisory mode operators and semiautomatic mode operators. If you will only use the device in manual mode or advisory mode you do not need to read Section 5. If you will only use the device in semi-automatic mode you do not need to read Sections 3, 4, or 6.

Please read thoroughly the safety considerations and warnings section.

Procedures for daily checkout and unit care are found in the Maintenance Section.

This manual is supplemented by manual inserts for options available on the M Series. These inserts contain additional warnings, precautions, and safety-related information.

Manual Updates

ZOLL Medical Corporation provides Manual Updates to inform customers of changes in device information and use. The updates are mailed to each registered **M Series** purchaser automatically. All users should carefully review each manual update to understand its significance and then file it in its appropriate section within this manual for subsequent reference.

Unpacking

Carefully inspect each container for damage. If the shipping container or cushion material is damaged, it should be kept until the contents have been checked for completeness and the instrument has been checked for mechanical and electrical integrity. If the contents are incomplete, if there is mechanical damage, or if the instrument does not pass its electrical self-test, U.S.A. customers should call ZOLL Medical Corporation (1-800-348-9011). International customers should contact the nearest ZOLL authorized representative. If the shipping container is damaged, also notify the carrier.

Accessories

Note: The terms "ZOLL Multi-Function Electrode (MFE) Pads" and "MFE Pads" are used interchangeably throughout this manual.

- Service Manual
- Internal Defibrillator Handles and Cable Assembly *
- Internal Defibrillator Electrodes: 3.0" (7.6 cm), 2.7" (6.8 cm), 2.0" (5.1 cm), 1.6" (4.0 cm), & 1.0" (2.5 cm) diameter.*
- Adult, Multi-Function pacing/defibrillation electrode pads (12 pair/box)
- Pediatric, Multi-Function pacing/ defibrillation electrode pads (6 pair/box)
- Adult Multi-Function pacing/defibrillation Stat Padz
- Multi-Function Cable assembly for use with Multi-Function pacing/defibrillation Electrode Pads*
- Base PowerCharger^{4x4}
- Base PowerCharger^{1x1}
- ECG Simulator
- Battery Management Program Manual
- Replacement battery packs*
- Smart Batteries
- AAMI Standard 3-lead ECG patient cable & 5-lead ECG patient cable
- IEC Standard 3-lead ECG patient cable & 5-lead ECG patient cable
- Carry Case

*** These accessories are considered safety-relevant components**

Symbols Used on the Equipment

Any or all of the following symbols may be used in this manual or on this equipment:

Type B patient connection

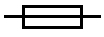
Type BF patient connection

Type CF patient connection

Defibrillation protected Type BF patient connection

Defibrillation protected Type CF patient connection

Attention Refer to manual for more information


Fusible Link

Protective (earth) ground terminal

DANGER High Voltage present

Alternating current

Conformité Européenne Complies with the medical device directive 93/42/EEC

Defibrillator Function

The **M Series** products contain a DC defibrillator capable of delivering up to 360 joules of energy. It may be used in synchronized mode to perform synchronized cardioversion by using the R-wave of the patient's ECG as a timing reference. The unit uses paddles or disposable, pre-gelled, MFE Pads for defibrillation.

Intended Use — Manual Operation

Use of the **M Series** products in the manual mode for defibrillation is indicated on victims of cardiac arrest where there is apparent lack of circulation as indicated by:

- Unconsciousness
- Absence of breathing
- Absence of pulse.

This product should be used only by qualified medical personnel for converting ventricular fibrillation and rapid ventricular tachycardia to sinus rhythm or other cardiac rhythms capable of producing hemodynamically significant heart beats.

Intended Use — Semiautomatic Operation (AED)

The **M Series** products are designed for use by emergency care personnel who have completed training and certification requirements applicable to the use of a defibrillator where the device operator controls delivery of shocks to the patient.

They are specifically designed for use in early defibrillation programs where the delivery of a defibrillator shock during resuscitation involving CPR, transportation, and definitive care are incorporated into a medically-approved patient care protocol.

The **M Series** products must be prescribed for use by a physician or medical advisor of an emergency response team.

Use of the device in the Semiautomatic mode for defibrillation is indicated on victims of cardiac arrest where there is apparent lack of circulation as indicated by:

- Unconsciousness
- Absence of breathing
- Absence of pulse.

Specifications for the ECG rhythm analysis function are provided at the end of this section.

Semiautomatic Operation Contraindications for Use

The rhythm analysis function may not reliably identify ventricular fibrillation in the presence of an implantable pacemaker. Inspection of the electrocardiogram and clinical evidence of cardiopulmonary arrest should be the basis for any treatment of patients with implantable pacemakers.

Do not use the rhythm analysis function during patient movement on a stretcher or in an ambulance or other conveyance. A patient must be motionless during ECG analysis. Do not touch the patient during analysis. Cease all movement via stretcher or vehicle prior to analyzing the ECG. If using the device in an emergency vehicle, bring the vehicle to a halt before activating the analysis function.

Note: Do not use the unit's AED function on patients under 8 years of age.

Defibrillator Complications

Inappropriate defibrillation or cardioversion of a patient (e.g., with no malignant arrhythmia) may precipitate ventricular fibrillation, asystole, or other dangerous arrhythmias.

Defibrillation without proper application of electrode pads or paddle electrolyte gel may be ineffective and cause burns, particularly when repeated shocks are necessary. Erythema or hyperemia of the skin under the paddles or MFE Pads often occurs; this effect is usually enhanced along the perimeter of the paddle or electrode. This reddening should substantially lessen within 72 hours.

Defibrillator Output Energy

The **M Series** products may deliver up to 360 joules into a 50 ohm impedance. The energy delivered through the chest wall, however, is determined by the patients transthoracic impedance. An adequate amount of electrolyte gel must be applied to the paddles and a force of 10-12 kilograms must be applied to each paddle in order to minimize this impedance. If MFE Pads are used, make sure that they are properly applied. (Refer to the instructions on the **Multi-Function Electrode** package).

External Pacemaker (Pacer Version Only)

Non-invasive Transcutaneous Pacing (NTP) is an established and proven technique. This therapy is easily and rapidly applied in both emergency and non-emergency situations when temporary cardiac stimulation is indicated.

Some **M Series** products may contain an optional demand pacemaker consisting of a pulse generator and ECG sensing circuitry. The output current of the pacemaker is continuously variable from 0 to 140 mA and the rate is continuously variable from 30 to 180 pulses per minute (ppm).

The pacing output pulse is delivered to the heart by specially designed ZOLL MFE Pads placed on the back and the precordium.

The characteristics of the output pulse, together with the design and placement of the electrodes, minimize cutaneous nerve stimulation, cardiac stimulation threshold currents, and reduce discomfort due to skeletal muscle contraction.

The unique design of the **M Series** products allow clear viewing and interpretation of the electrocardiogram (ECG) on the display without offset or distortion during external pacing.

Proper operation of the device, together with correct electrode placement, is critical to obtaining optimal results. Every operator must be thoroughly familiar with these operating instructions.

Intended Use — Pacemaker

This product may be used for temporary external cardiac pacing in conscious or unconscious patients as an alternative to endocardial stimulation.

Note: This device must not be connected to internal pacemaker electrodes.

The purposes of pacing include:

Resuscitation from standstill or bradycardia of any etiology:

Noninvasive pacing has been used for resuscitation from cardiac standstill, reflex vagal standstill, drug induced standstill (due to procainamide, quinidine, digitalis, b-blockers, verapamil, etc.) and unexpected circulatory arrest (due to anesthesia, surgery, angiography, and other therapeutic or diagnostic procedures). It has also been used for temporary acceleration of bradycardia in Stokes-Adams disease and sick-sinus syndrome. It is safer, more reliable, and more rapidly applied in an emergency than endocardial or other temporary electrodes.

As a standby when standstill or bradycardia might be expected:

Noninvasive pacing may be useful as a standby when cardiac arrest or symptomatic bradycardia might be expected due to acute myocardial infarction, drug toxicity, anesthesia or surgery. It is also useful as a temporary treatment in patients awaiting pacemaker implants or the introduction of transvenous therapy. In standby pacing applications, noninvasive pacing may provide an alternative to transvenous therapy that avoids the risks of displacement, infection, hemorrhage, embolization, perforation, phlebitis and mechanical or electrical stimulation of ventricular tachycardia or fibrillation associated with endocardial pacing.

Suppression of tachycardia:

Increased heart rates in response to external pacing often suppress ventricular ectopic activity and may prevent tachycardia.

Pacemaker Complications

Ventricular fibrillation will not respond to pacing and requires immediate defibrillation. The patient's dysrhythmia must therefore be determined immediately, so that appropriate therapy can be employed. If the patient is in ventricular fibrillation and defibrillation is successful, but cardiac standstill (asystole) ensues, the pacemaker should be used.

Ventricular or supraventricular tachycardias may be interrupted with pacing but in an emergency or during circulatory collapse, synchronized cardioversion is faster and more certain. (See Synchronized Cardioversion Section.)

Electromechanical dissociation may occur following prolonged cardiac arrest or in other disease states with myocardial depression. Pacing may then produce ECG responses without effective mechanical contractions, and other treatment is required.

Pacing may evoke undesirable repetitive responses, tachycardia, or fibrillation in the presence of generalized hypoxia, myocardial ischemia, cardiac drug toxicity, electrolyte imbalance, or other cardiac diseases.

Pacing by any method tends to inhibit intrinsic rhythmicity. Abrupt cessation of pacing, particularly at rapid rates, can cause ventricular standstill and should be avoided.

Noninvasive Temporary Pacing may cause discomfort of varying intensity, which occasionally can be severe and preclude its continued use in conscious patients.

Similarly, unavoidable skeletal muscle contraction may be troublesome in very sick patients and may limit continuous use to a few hours. Erythema or hyperemia of the skin under the MFE Pads often occurs; this effect is usually enhanced along the perimeter of the electrode.

This reddening should substantially lessen within 72 hours.

There have been reports of burns under the anterior electrode when pacing adult patients with severely restricted blood flow to the skin. Prolonged pacing should be avoided in these cases and periodic inspection of the skin is advised.

There are reports of transient inhibition of spontaneous respiration in unconscious patients with previously available units when the anterior electrode was placed too low on the abdomen.

This device must not be connected to internal pacemaker electrodes.

Pediatric Pacing

Pacing can be performed on pediatric patients weighing 33lbs / 15kg or less using special ZOLL pediatric MFE Pads. Prolonged pacing (in excess of 30 minutes), particularly in neonates, could cause burns. Periodic inspection of the underlying skin is recommended.

Monitor

The patient's ECG is monitored by connecting the patient to the unit via the 3 or 5 lead patient cable, MFE Pads, or through the paddles. Four seconds of ECG is presented on the display along with the following information:

- averaged heart rate, derived from measuring R to R intervals
- lead selections - I, II, III, aVR, aVL, aVF, V (with ECG cable), PADDLES, or PADS
- ECG size - 0.5, 1, 1.5, 2, 3 cm/mV
- pacemaker output in milliamps (Pacer version only)
- pacemaker stimulus rate in pulses per minute (Pacer versions only)
- defibrillator output in joules
- other operational prompts, messages, and diagnostic codes

Monitoring or diagnostic ECG bandwidth is selectable.

Recorder Function

A strip recorder is provided to document events. The strip recorder normally operates in the delay mode (6 seconds) to insure capture of critical ECG information. The recorder may be activated manually by pressing the **RECORDER** button. It will be activated automatically whenever a defibrillation **SHOCK** is delivered, a heart rate alarm occurs, or the rhythm analysis function is activated. The strip recorder may also be configured not to print during these events.

Paddle - Electrode Options

The **M Series** products will defibrillate, cardiovert and monitor ECG using either defibrillation paddles or ZOLL Multi-Function Electrode (MFE) Pads.

The pacer version of the **M Series** will also pace using ZOLL MFE Pads.

Energy Select, Charge, and Shock controls are located on the paddles and front panel. When using MFE Pads, the controls on the front panel of the unit must be used. To switch between paddles and MFE Pads, remove Multi-Function cable from the apex paddle and connect the MFE pads to the Multi-Function cable.

The Advisory function cannot be activated unless MFE Pads are attached to the Multi-Function Cable and used as the ECG monitoring lead.

Note: The MFE Pads, Pediatric MFE Pads, Stat Padz, and ECG electrodes (not the ECG cable) are disposable, single-use items.

Batteries

The **M Series** products use easily replaced sealed, lead-acid battery packs that, when new and fully charged, will provide at least 2.5 hours of monitoring. Use of the defibrillator, strip chart recorder, and pacemaker will reduce this time.

When a "LOW BATTERY" message appears on the display and the unit emits two beeps in conjunction with the displayed message, the battery must be replaced and recharged.

Internal Battery Charger

Battery charging can be performed within the device via AC mains, an optional DC input, or by using an external battery charger.

When the **M Series** products are plugged into AC mains or to a DC power supply, the **CHARGER ON** indicators will operate in the following manner:

The orange-yellow **CHARGER ON** indicator will illuminate continuously whenever; the device is turned OFF and charging the battery or turned ON with a battery installed.

The green **CHARGER ON** indicator will illuminate continuously whenever the unit is turned OFF and the installed battery has been fully charged to present capacity.

The green and orange-yellow **Charger On** indicators will illuminate alternately when **no** battery is installed in the unit or a battery charging fault has been detected.

When the device is not connected to AC mains, the **CHARGER ON** indicators will remain extinguished.

If your M Series unit does not function as expected, see the AC Charger Troubleshooting section on page 11-7.

External Battery Charger

External battery charging and capacity evaluation is performed with the ZOLL Base PowerCharger^{4x4}. Up to four battery packs can be charged simultaneously and testing is automatic. See the appropriate ZOLL battery charger Operator's Guide and Battery Management Program for more detailed information on the specifications, use and management of ZOLL battery packs.

Diagnostics

A computer contained within the unit performs self-diagnostic tests whenever the product is initially turned on and periodically during operation. During operation, a "*Function** FAULT XX" message will be displayed if a fault is detected. If this occurs, turn the unit off and then on and recheck operation. Contact authorized service personnel if the message continues to be displayed.

**** Function:* may include Recorder, Pace, Defib, etc.**

Safety Considerations

The **M Series** products are high energy devices capable of delivering up to 360 joules. To completely deactivate the device, you must turn the **SELECTOR SWITCH** to the **OFF** position.

In order to disarm a charged defibrillator:

- Turn the **SELECTOR SWITCH** to **MONITOR, OFF** or **PACER** (pacer equipped versions only)
  or
- Change the selected defibrillator energy

As a safety feature, the device will automatically disarm if left charged for more than 60 seconds (15 seconds for AED versions).

Note: The terms "ZOLL Multi-Function Electrode (MFE) Pads" and "MFE Pads" will be used interchangeably throughout this manual.

WARNINGS

General

- Federal (U.S.A.) law restricts this device to use by or on the order of a physician.
- The use of external pacing/defibrillation electrodes or adapter devices from sources other than ZOLL is not recommended. ZOLL makes no representations or warranties regarding the performance or effectiveness of its products when used in conjunction with pacing/defibrillation electrodes or adapter devices from other sources. Device failures attributable to the use of pacing/defibrillation electrodes or adapters not manufactured by ZOLL may void ZOLL's warranty.
- Proper operation of the unit, together with correct electrode placement is critical to obtaining optimal results. Operators must be thoroughly familiar with proper device operation.
- Do not use the unit in semiautomatic mode during patient movement. A patient must be motionless during ECG analysis. Do not touch the patient during analysis. Cease all movement via stretcher or vehicle before analyzing the ECG. If using the device in an emergency vehicle, bring the vehicle to a halt before using in semiautomatic mode.
- The device is protected against interference from radio frequency emissions typical of two-way radios and cellular phones (digital and analog) used in emergency service/public safety activities. Users should assess the device's performance in their typical environment of use for the possibility of radio frequency interference from high-power sources. Radio Frequency Interference (RFI) may be observed as shifts in monitor baseline, trace compression, display brightness changes or transient spikes on the display.
- Do not operate the unit without a battery. Keep a fully charged spare battery pack with the device at all times.
- Regular use of partially charged battery packs without fully recharging between uses will result in permanently reduced capacity and early battery pack failure.
- Test batteries regularly. Batteries that do not pass ZOLL's capacity test could unexpectedly shutdown without warning.
- Replace the battery with a fully charged battery immediately after the "LOW BATTERY" or "REPLACE BATTERY" message.
- Emergency defibrillation should be attempted only by appropriately trained, skilled personnel who are familiar with equipment operation. Training appropriateness, such as Advanced Cardiac Life Support (ACLS) or Basic Life Support (BLS) certification, should be determined by the prescribing physician.
- Synchronized cardioversion should only be attempted by skilled personnel trained in Advanced Cardiac Life Support (ACLS) and familiar with equipment operation. The precise cardiac arrhythmia must be determined before attempting defibrillation.
- Prior to attempting synchronized cardioversion, ensure that the ECG signal quality is good and that sync marks are displayed above each QRS complex.
- These operating instructions describe the functions and proper operation of the **M Series** products. They are not intended as a substitute for a formal training course. Operators should obtain formal training from an appropriate authority prior to using the device for patient care.
- Do not disassemble the unit. A shock hazard exists. Refer all problems to authorized service personnel.
- Follow all recommended maintenance instructions. If a problem occurs, obtain service immediately. Do not use the device until it has been inspected by the appropriate personnel.
- Do not use the unit's ECG out signal as a sync pulse for another defibrillator or cardioverter.

WARNINGS (Continued)

- The ECG out signal is delayed by up to 25 ms. This delay must be considered when the ECG out signal is used as an input to other devices requiring R-wave synchronization.
- The **M Series** device may not perform to specifications when stored at the upper or lower extreme limits of storage temperature and immediately put into use.

Operator Safety

- Do not use **M Series** products in the presence of oxygen-rich atmospheres, flammable anesthetics or other flammable agents (such as gasoline). Using the instrument near the site of a gasoline spill may cause an explosion.
- Do not use the instrument near or within puddles of water. Electrical safety of the device may be compromised when wet.
- Do not discharge with paddles or MFE Pads shorted together or in open air.
- Warn all persons in attendance of the patient to STAND CLEAR prior to defibrillator discharge.
- Do not touch the bed, patient, or any equipment connected to the patient during defibrillation. A severe shock can result. Do not allow exposed portions of the patient's body to come in contact with metal objects, such as a bed frame, as unwanted pathways for defibrillation current may result.
- For defibrillation using paddles, utilize only high conductivity electrolyte gel specified by the manufacturer for such use.
- To avoid risk of electrical shock, do not allow electrolyte gel to accumulate on hands or paddle handles.
- To avoid risk of electrical shock, do not touch the gelled area of the MFE Pads while pacing.
- When defibrillating with paddles use your thumbs to operate the SHOCK buttons in order to avoid inadvertent operator shock. No portion of the hand should be near the paddle plates.
- Only use thumbs to depress the paddle **SHOCK** buttons. Failure to do so could result in the inadvertent depression of the energy select buttons, causing the defibrillator to disarm itself.
- Do not discharge the defibrillator except as indicated in the instructions. Do not discharge the defibrillator if the MFE Pads are not properly attached to the patient.
- Always check that the equipment functions properly and is in proper condition before use.
- Disconnect all electro-medical equipment that is not defibrillation protected from the patient prior to defibrillation.
- The use of ACCESSORY equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:
  - Use of the accessory in the PATIENT VICINITY
  - Evidence that the safety certification of the ACCESSORY has been performed in accordance with the appropriate IEC (EN) 60601-1 and/or IEC (EN) 60601-1-1 harmonized national standards.

Patient Safety

- Neonatal and pediatric defibrillation energy levels should be set based on site-specific clinical protocols.
- Do not use the unit's AED function on patients under 8 years of age**. ***
- The device detects ECG electrical signals only. It will not detect a pulse (i.e. effective circulatory perfusion). Always verify pulse and heart rate by physical assessment of the patient. Never assume that a non-zero heart rate display means that the patient has a pulse.
- Implanted pacemakers may cause the heart rate meter to count the pacemaker rate during incidents of cardiac arrest or other arrhythmias. Pacemaker patients should be carefully observed. Check the patient's pulse; do not rely solely on heart rate meters. Dedicated pacemaker detection circuitry may not detect all implanted pacemaker spikes. Patient history and physical exam are important in determining the presence of an implanted pacemaker.
- Use only high quality ECG electrodes. ECG electrodes are for rhythm acquisition only. Do not attempt to defibrillate or pace through ECG electrodes.
- The ECG rhythm analysis function does not warn the operator of patient asystole, as it is not a shockable rhythm.
- Do not use ECG electrodes or MFE Pads if the gel is dried, separated, torn, or split from the foil; patient burns may result from using such electrodes. Poor adherence and/or air under the MFE Pads can lead to the possibility of arcing and skin burns.
- Excessive body hair or wet, sweaty skin can inhibit good coupling (contact), which can lead to the possibility of arcing and skin burns. Clip excess hair and dry surrounding moisture from the area where the electrode is to be attached.
- MFE Pads should be replaced after 8 hours of continuous pacing (2 hours for Radiolucent *stat***z***pad***z**) to ensure maximum patient benefit.

*** AHA Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care, I-64, 2000.**

WARNINGS (Continued)

- To avoid electrosurgery burns at monitoring sites, ensure proper connection of the electrosurgery return circuit so that the return paths cannot be made through monitoring electrodes or probes.
- Prolonged pacing (in excess of 30 minutes), particularly in neonates or adults with severely restricted blood flow, may cause burns. Periodic inspection of the underlying skin is recommended.
- Check leakage levels prior to use. Leakage current may be excessive if more than one monitor or other piece of equipment is connected to the patient.

CAUTIONS

- Do not install the battery into the device when storage may exceed 90 days. Battery damage may occur.
- The "LOW BATTERY" message display-to-shutdown interval may be less than one minute when older batteries become depleted.
- The M Series ships standard with a PD 4410 battery, but can optionally use the XL battery if properly configured. Incorrectly configuring the unit for XL battery operation when the PD 4410 is installed substantially reduce the number of defibrillation shocks that can be delivered between the onset of the "LOW BATTERY" warning message and M Series shutdown. (See the M Series Configuration Guide, P/N 9650-0201-01, for complete details on properly configuring the selected battery type.)
- Do not sterilize the device.
- Do not immerse any part of the device in water.
- Do not use alcohol or ketones (MEK, acetone, etc.) on the device.
- Avoid using abrasives (e.g. paper towels) on the display window.
- Grounding reliability can only be achieved when the equipment is connected to an equivalent receptacle marked "HOSPITAL ONLY" or "HOSPITAL GRADE". If the grounding integrity of the line cord or AC receptacle is in doubt, operate on battery only.
- Use only ECG cables (namely, ones with internal current-limiting resistors) specified or supplied by ZOLL Medical Corporation to protect the M Series from damage during defibrillation, for accurate ECG information, and for protection against noise and other interference.

Restarting the Device

Certain events require the **M Series** products to be restarted after they shut off or become inoperative.

One example is when the battery runs down and the unit shuts off. The selector switch should always be turned to the OFF position before removing the battery. The selector switch may then be turned to the desired operating mode to resume operation after insertion of a new battery. This sequence is needed to restart the device, and can also be used to clear some "X FAULT XX" messages, if immediate use of the device is required.

Note that some settings (for example, alarm settings, lead selection, ECG size) may need to be restored from their default values when operation is resumed.

FDA Regulations

Tracking Requirements

U.S. Federal Law (21 CFR 821) requires the tracking of defibrillators. As an owner of this device, you have the responsibility under this law to notify ZOLL Medical Corporation if this product has been received; lost, stolen or destroyed; or has been donated, resold, or otherwise distributed to a different organization.

If any of the events described above occur, please contact ZOLL Medical Corporation in writing with the following information:

1. Originator's organization - Company Name, Address, Contact Name, and Contact Phone Number
2. Part Number/Model Number and Serial Number
3. Disposition of Device (e.g., received, lost, stolen, destroyed, distributed to another organization), New Location and/or Organization (if different from #1 above) - Company Name, Address, Contact Name, and Contact Phone Number
4. Date change took effect
5. Other information or comments

Please address your information to:

ZOLL Medical Corporation
Attn: Tracking Coordinator
269 Mill Road
Chelmsford, MA 01824-4105

Fax: (978) 421-0010
Tel: (978) 421-9655

Notification of Adverse Events

As a health care provider, you may have responsibilities under the SMDA, for reporting to ZOLL and possibly to the FDA the occurrence of certain events.

These events, described in 21 CFR Part 803, include device related death and serious injury or illness. In any event, as part of our Quality Assurance Program, ZOLL should be notified of any device failures or malfunctions. This information is required to assure that ZOLL provides only the highest quality products.

Warranty (U.S. Only)

(a) ZOLL Medical Corporation warrants to the original equipment purchaser that beginning on the date of installation, or thirty (30) days after the date of shipment from ZOLL Medical Corporation's facility, whichever first occurs, the equipment (other than accessories and electrodes) will be free from defects in material and workmanship under normal use and service for the period of one (1) year. During such period ZOLL Medical Corporation will, at no charge to the customer, either repair or replace (at ZOLL Medical Corporation's sole option) any part of the equipment found by ZOLL Medical Corporation to be defective in material or workmanship. If ZOLL Medical Corporation's inspection detects no defects in material or workmanship, ZOLL Medical Corporation's regular service charges shall apply. (b) ZOLL Medical Corporation shall not be responsible for any equipment defect, the failure of the equipment to perform any function, or any other nonconformance of the equipment, caused by or attributable to: (i) any modification of the equipment by the customer, unless such modification is made with the prior written approval of ZOLL Medical Corporation; (ii) the use of the equipment with any associated or complementary equipment, (iii) installation or wiring of the equipment other than in accordance with ZOLL Medical Corporation's instructions. (c) This warranty does not cover items subject to normal wear and burnout during use, including but not limited to lamps, fuses, batteries, patient cables and accessories. (d) The foregoing warranty constitutes the exclusive remedy of the customer and the exclusive liability of ZOLL Medical Corporation for any breach of any warranty related to the equipment supplied hereunder. (e) Limitation of Liability: ZOLL shall not in any event be liable to Purchaser, nor shall Purchaser recover, for special, incidental or consequential damages resulting from any breach of warranty, failure of essential purpose, or under any other legal theory including but not limited to lost profits, lost savings, downtime, goodwill, damage to or replacement of equipment and property, even if ZOLL has been advised of the possibility of such damages.

THE WARRANTY SET FORTH HEREIN IS EXCLUSIVE AND ZOLL MEDICAL CORPORATION EXPRESSLY DISCLAIMS ALL OTHER WARRANTIES WHETHER WRITTEN, ORAL, IMPLIED, OR STATUTORY, INCLUDING BUT NOT LIMITED TO ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

For additional information, please call ZOLL Medical Corporation at 1-800-348-9011. International customers should call the nearest authorized ZOLL Medical Corporation service center.

Software License

Note: Read this Operator's Manual and License agreement carefully before operating any of the M Series products.

Software incorporated into the system is protected by copyright laws and international copyright treaties as well as other intellectual property laws and treaties. This software is licensed, not sold. By taking delivery of and using this system, the Purchaser signifies agreement to and acceptance of the following terms and conditions:

1. **Grant of License:** In consideration of payment of the software license fee which is part of the price paid for this product ZOLL Medical Corporation grants the Purchaser a non-exclusive license, without right to sublicense, to use the system software in object-code form only.

2. **Ownership of Software/Firmware:** Title to, ownership of and all rights and interests in the system software and all copies thereof remain at all times vested in the manufacturer, and Licensors to ZOLL Medical Corporation and they do not pass to Purchaser.

3. **Assignment:** Purchaser agrees not to assign, sub-license or otherwise transfer or share its rights under the license without the express written permission of ZOLL Medical Corporation.

4. **Use Restrictions:** As the Purchaser, you may physically transfer the products from one location to another provided that the software/firmware is not copied. You may not disclose, publish, translate, release or distribute copies of the software/firmware to others. You may not modify, adapt, translate, reverse engineer, decompile, crosscompile, disassemble or create derivative works based on the software/firmware.

Service

The device does not require periodic recalibration or adjustment. Appropriately trained and qualified personnel should, however, perform periodic tests of the device to verify proper operation. (See **General Maintenance** Section).

U.S.A. Customers

Should the unit require service, it should be returned, in its original container, to:

ZOLL Medical Corporation
269 Mill Road
Chelmsford, Massachusetts 01824-4105,
Attn: Technical Service Department

Loaner instruments are available for use while repairs are being completed. To request loan equipment, contact the ZOLL Technical Service Department at 1-800-348-9011. Have the following information available to expedite service:

- The device's serial number
- A description of the problem
- Department where equipment is in use
- Sample ECG strips documenting problem (if available)
- A Purchase Order to allow tracking of loan equipment

International Customers

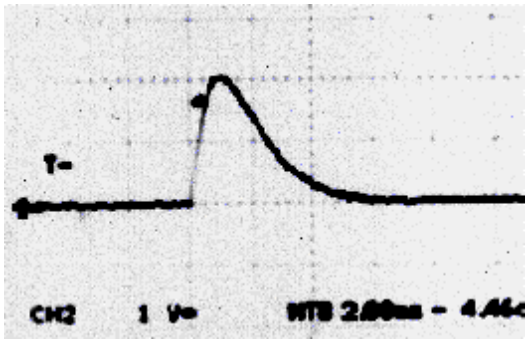
Should the unit require service, return it, in its original container, to the nearest authorized ZOLL Medical Corporation service center.

Defibrillator Waveform Information

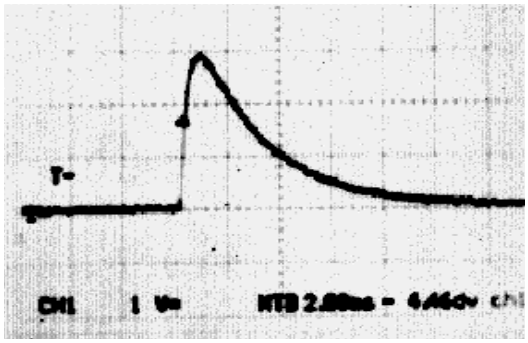
General

The following defibrillation waveforms are produced when the device is discharged into 25, 50 and 100 ohm loads at maximum energy. Each major vertical division equals 1000 volts; each major horizontal division equals 2 milliseconds.

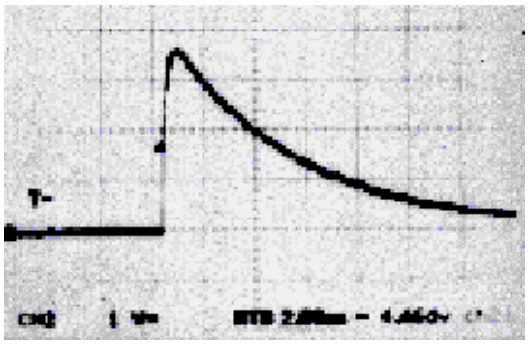
Discharge into a 25 ohm load



Discharge into a 50 ohm load



Discharge into a 100 ohm load



ECG Analysis Algorithm Accuracy

Sensitivity, specificity, false positive rate and positive predictivity are expressions of the accuracy of an ECG analysis system when compared with clinicians or experts. The specifics of computations are detailed below. The accompanying data details the accuracy of the algorithm as tested by independent investigators.

The Algorithm:

- Divides the ECG rhythm into three 3-second segments.
- Filters and measures noise, artifact, and baseline wander.
- Measures baseline content ('waviness' at the correct frequencies- frequency domain analysis) of signal.
- Measures QRS rate, width, and variability.
- Measures amplitude and temporal regularity ('auto-correlation') of peaks and troughs.
- Determines if two-out of-three, 3 second segments are shockable then displays "SHOCK ADVISED" message.

The Algorithm sequence takes approximately 9 seconds.

Clinical Performance Results

Applications:	**# of analyses**	**# of patients**
	316	194

Shockable Rhythm

Overall Sensitivity	95.7%
Positive Predictability	100.0%

Non-shockable Rhythm

Overall Sensitivity	100%
False Positive Rate	0%

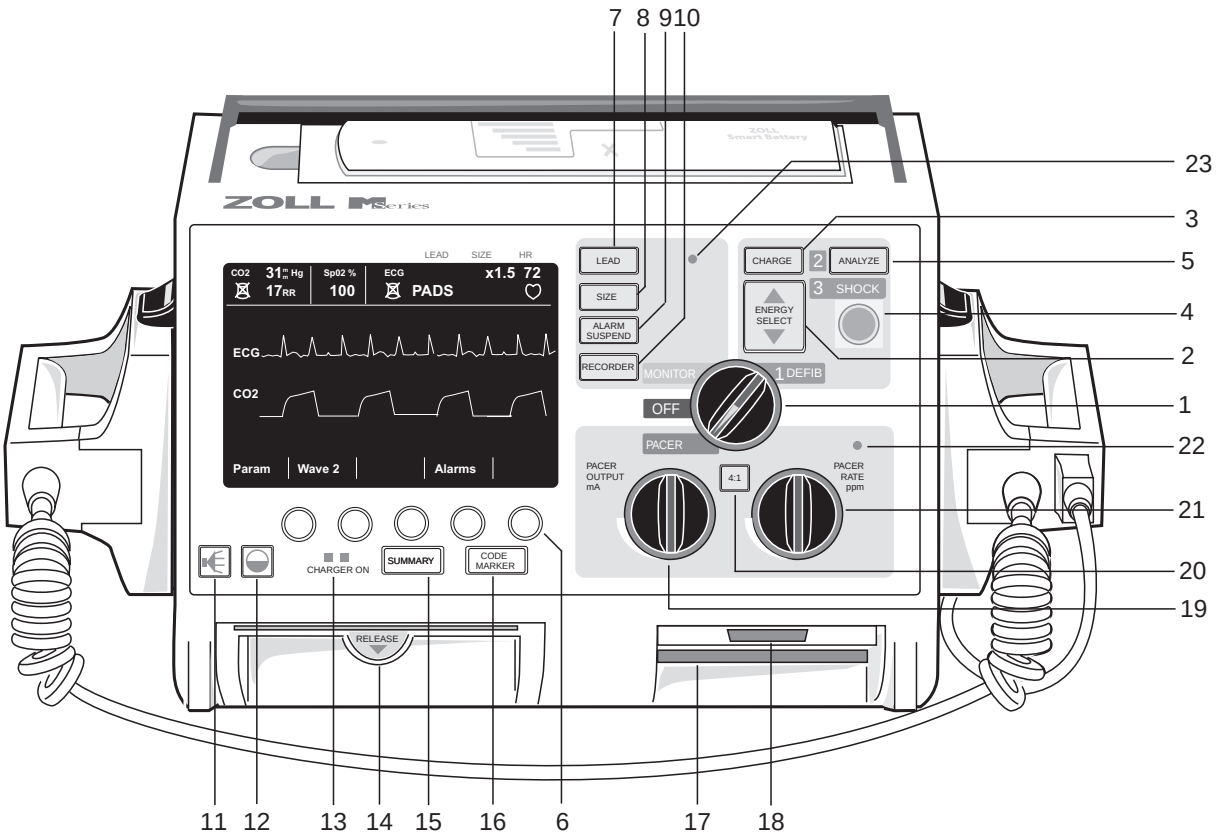
Sensitivity = # of "correct shock" decisions by algorithm / Total # of rhythms for which a shock is clinically advised

Specificity = # of "correct no shock" decisions by algorithm / Total # of rhythms for which no shock is clinically advised

False Positive Rate = # of "incorrect shock" decisions by algorithm / Total # of rhythms for which no shock is clinically advised

Positive Predictivity = # of "correct shock" decisions by algorithm / Total # of rhythms for which shock is advised by unit

SECTION 2
OPERATING CONTROLS AND INDICATORS



1. SELECTOR SWITCH

The selector switch allows selection of the following modes: **OFF, MONITOR, DEFIB**, and **PACER**, (Pacer version only)

2. DEFIB ENERGY SELECT BUTTONS

Two sets of up-down arrow buttons control the defibrillator energy level, one set located on the front panel and the other located on the sternum paddle.

Press and hold the appropriate up ▲ or down ▼ arrow button until the desired energy level is indicated on the display.

3. DEFIB CHARGE

Pressing the **CHARGE** button on the front panel or, if using paddles, on the apex paddle handle, charges the defibrillator to the selected energy level.

4. SHOCK

The **SHOCK** button illuminates when the defibrillator is charged and ready. Press and hold the button to discharge the defibrillator.

The **SHOCK** button is only active when using Multi-Function Electrodes (MFE) Pads, external autoclavable paddles, or internal defibrillation paddles without a discharge button. The **SHOCK** button is not functional when external paddles are connected to the unit.

Each external paddle has a **SHOCK** button located near the forward end of the handle. Press and hold both buttons simultaneously to discharge the defibrillator.

5. ANALYZE

The **ANALYZE** button initiates ECG analysis to identify shockable rhythms.

6. SOFTKEYS

Five unlabeled buttons located directly beneath the display control different functions depending on the operating mode of the unit. Labels for the softkeys appear at the bottom of the display directly above each softkey to indicate its function.

7. LEAD

The **LEAD** button determines selection of the ECG source. Pressing this button sequentially selects ECG signals derived from each of the following lead configurations - "I", "II", "III", "aVR, aVF, aVL, PADDLES" (defibrillator paddles), or "PADS" (Multi-Function Electrode (MFE) Pads) for display. The "PADS" or "PADDLES" Lead setting is automatically selected when the instrument powers up in **DEFIB** or **MONITOR** mode and MFE Pads or Paddles are connected to the Multi-Function cable.

Lead II is automatically selected when the M Series unit powers up in **PACER** mode (Pacer version only). Pads or Paddles monitoring is **not** available in **PACER** mode.

8. SIZE

The **SIZE** button allows you to change the display size of the ECG signal. Size options are 0.5, 1, 1.5, 2, 3 cm/mV and are indicated in the upper right center of the display.

9. ALARM SUSPEND

The **ALARM SUSPEND** button is used to activate, deactivate and audibly suspend all alarm functions. A bell symbol (🔔) appears in the top-center of the display when the alarms are enabled. When the alarms are either audibly or permanently disabled, an "X" crosses through the bell (🔕) symbol.

When the alarms are enabled, and an alarm condition occurs, an audible tone sounds and the bell symbol flashes. To avoid possible confusion with the defibrillator charged tone, the heart rate alarm tone sounds at a different frequency when the Selector Switch is set to **DEFIB**.

10. RECORDER

This control starts and stops the strip recorder. There is a **RECORDER** button located on the unit's front panel and another located on the sternum paddle.

The unit can be switched to diagnostic ECG bandwidth (0.05-150 Hz) by pressing and holding the **RECORDER** button.

Diagnostic bandwidth is maintained as long as the **RECORDER** button is held down. The unit reverts to standard monitoring bandwidth when the **RECORDER** button is released.

11. BEEPER VOLUME (ECG)

This button allows for manual adjustment of the QRS beeper tone from maximum volume to inaudible. (The heart rate alarm and charge ready volumes are not adjustable.) Press this button to display a menu for adjusting the volume using softkeys.

12. BRIGHTNESS/CONTRAST ADJUSTMENT

This button causes a menu to appear on the display for adjusting the display brightness using softkeys (contrast on LCD).

13. CHARGER ON

When the **M Series** products are plugged into AC mains, the **CHARGER ON** indicators will operate in the following manner:

The orange-yellow **CHARGER ON** indicator will illuminate continuously whenever; the device is turned OFF and charging the battery or turned ON with a battery installed.

The green CHARGER ON indicator will illuminate continuously whenever; the unit is turned OFF and the installed battery has been fully charged to present capacity.

The green and orange-yellow **CHARGER ON** indicators will illuminate alternately when; **no** battery is installed in the unit or a battery charging fault has been detected.

When the device is not connected to AC mains, the **CHARGER ON** indicators will remain extinguished.

14. Paper Tray

Holds the paper supply for the recorder. Press down and pull to open the drawer and replace the paper.

15. SUMMARY

The **SUMMARY** button retrieves stored patient information and prints it on the unit recorder as a Summary Report. The Summary Report function automatically collects critical patient ECG data, control settings, date, time and therapies administered during certain events.

See the "Summary Report" section for more information.

16. CODE MARKER

The **CODE MARKER** button activates a menu and softkeys that allow the unit to record in its internal memory the delivery of specific drugs or treatments.

See the "Code Markers" section for more information.

17. PCMCIA Data Card Slot

Holds the PCMCIA flash memory card for data storage and retrieval.

18. PC Card Modem Slot (12-Lead Option Only)

Holds the modem card for transmitting 12-Lead ECG information to remote locations via landline or cellular phone. See the *12-Lead ECG Monitoring* insert (part number 9650-0215-01) for more information.

Note: The modem slot is covered by a plastic bezel.

19. PACER OUTPUT mA (Pacer Version Only)

When pacing is selected, this control sets the amount of current delivered to the MFE Pads. For conscious patients, it should be gradually increased until capture is recognized. The selected current setting is indicated on the display.

20. 4:1 BUTTON (Pacer Version Only)

This control is used to test for threshold or to determine the patient's underlying rhythm. When depressed this button causes pacing stimuli to be delivered at ¼ the indicated ppm setting. Releasing the control causes the instrument to resume normal pacing operation.

21. PACER RATE ppm (Pacer Version Only)

When pacing is selected, this control sets the rate at which the pacemaker will operate. It must be set above the patient's intrinsic rate in order for the pacemaker to provide stimulation. The selected pace rate setting is indicated on the display.

22. Systole and Alarm Speaker

Emits audible heart rate tone during ECG monitoring, and audible alarm indications when an alarmed condition occurs.

23. Microphone (Optional)

Records audio activity in the vicinity of the M Series unit for storage in non-volatile memory and on the PCMCIA data card.

CHARGE INDICATOR LIGHT (Not Shown)

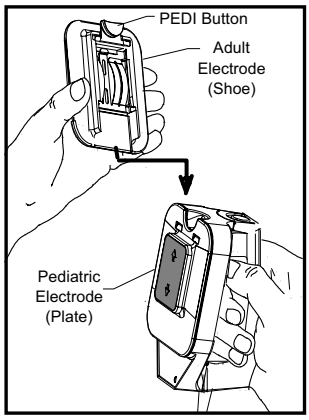
Located on the apex paddle, this light turns on when the defibrillator is charged and ready.

DEFIBRILLATOR TEST PORT (Not Shown)

Located on the Multi-Function Cable, the test connector is used to test the defibrillator output using the Multi-Function Cable only.

PEDIATRIC PADDLES (Not Shown)

Pediatric-size electrodes are built into the paddle assembly. They lie directly under the adult electrode surface and are accessed by pushing the black PEDI button at the front of each paddle and sliding the adult surface forward. When replacing the adult electrodes, it is important that the electrode is locked correctly in position on the paddle handle.



VOLT ECG OUT (Not Shown)

A 1 volt/cm of displayed ECG signal output is available from a subminiature phone jack located on the back of the device. This output may be used for interconnections to patient monitors and radio-telemetry equipment. The tip carries the ECG signal and the sleeve is ground.

Code Markers

Pressing the **CODE MARKER** button causes the unit to display a preconfigured list of clinical actions. Pressing the softkey associated with a particular action causes that action to be recorded along with a date and time stamp in the Summary Report Memory.

Up to five Code Markers can be displayed on the screen at one time. The right-most softkey is labeled "MORE" when there are more than five items on the Code Marker list. Pressing the MORE softkey will cause the next set of Code Markers to be displayed above the softkeys. Separate Code Marker lists are maintained for PACER, MONITOR, and DEFIB modes thereby enabling the appropriate Code Markers to be displayed for the particular protocol (e.g. PACE: EPI, Atrop MONITOR: Valium, LIDO DEFIB: BRET, AMIO).

The Code Markers are removed from the display after 10 seconds. If no Code Marker softkey has been pressed in that time, a generic event MARK is stored in Summary Report memory.

Summary Report

Summary Report allows you to store and later retrieve important ECG and device event information. The unit's internal memory automatically records defibrillation and cardioversion segments, **PACER** mode (Pacer version only), heart rate alarm and ECG segments upon activation of the strip chart recorder. Associated event information including device control settings, patient ECG, time and date are recorded as well.

Note: Diagnostic bandwidth recordings are not included in Summary Report.

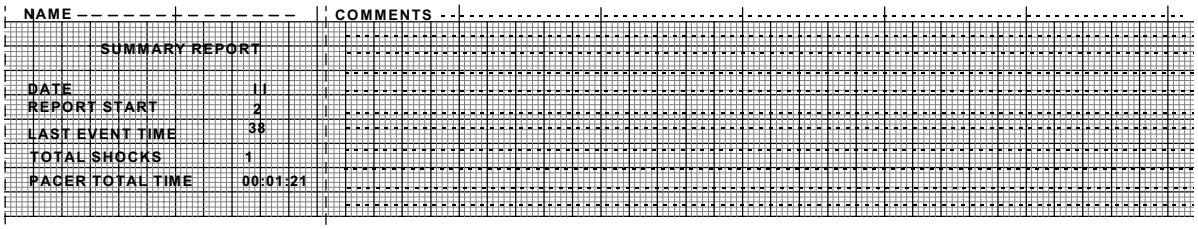
Six events will trigger Summary Report to automatically record information:

- VF Alarm triggered
- Defibrillator Shock
- Selecting **PACER** mode (Pacer version only)
- Heart Rate Alarm triggered
- Turning Strip Recorder on (or on and then off in rapid sequence)
- Initiating analysis of the ECG

Summary Report records each event in chronological order and will store up to 65 defibrillation or 140 recorder activated ECG events. All event data will remain in memory and be accessible until data is manually erased. A new patient record is automatically created if the unit has been turned off for a user configurable time period of 5 minutes to 36 hours. If all memory has been used for a particular patient, a "REPORT FULL" message will appear on the display and no further data is recorded.

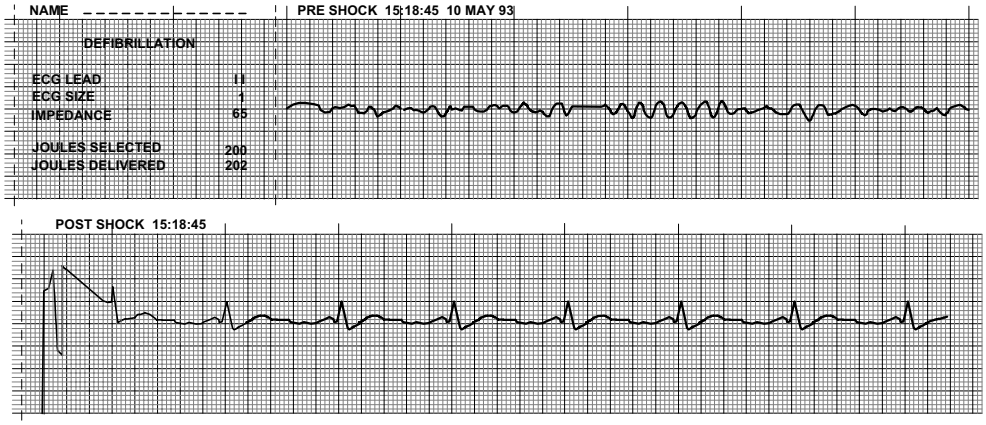
Summary Report Formats

Summary Report prints an overview of all the events currently stored in memory including total number of defibrillation shocks delivered, total pacing time (cumulative), time and date the device was turned on (or if you have just manually erased summary reports, then start time and date of the next report), time of last event, as well as space for patient name, date and comments. All segments have vertical dashed cut lines every 8.5 inches to facilitate easy mounting on 8.5" x 11" paper. On the last event recorded "SUMMARY COMPLETE" will be printed at the bottom left of the recorder strip.



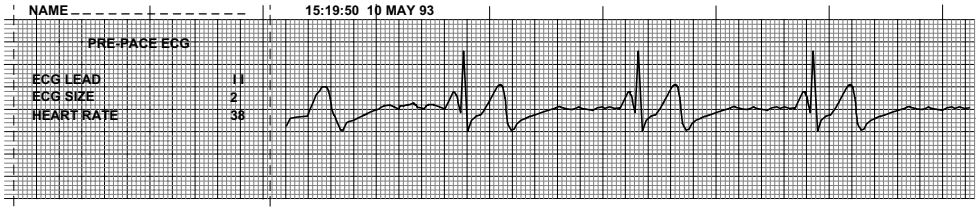
Defibrillation Format

Summary Report records six (6) seconds of pre-shock and eight (8) seconds of post-shock patient ECG data. Also recorded are joules selected, joules delivered, sync if active, (includes sync markers), ECG lead, ECG size, patient impedance, time and date. AED units will additionally include shock count and AED mode annotations.

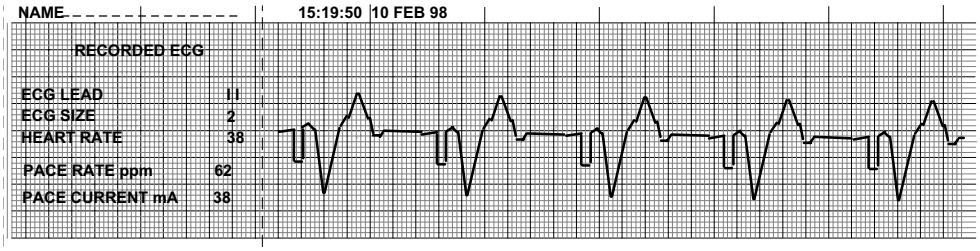


Pacer Format (Pacer version only)

Summary Report records six (6) seconds of pre-pacer patient ECG data. Also recorded are the ECG lead, ECG size, patient's heart rate, time and date.

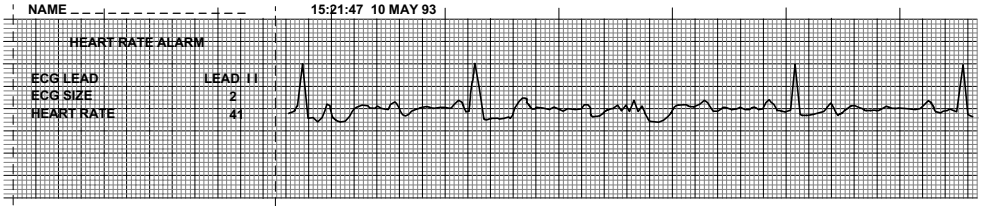


After establishing a paced rhythm, turning the recorder on briefly will record the paced rhythm for later reports. If async pace is active, the annotation “ASYNC PACE” is also recorded.



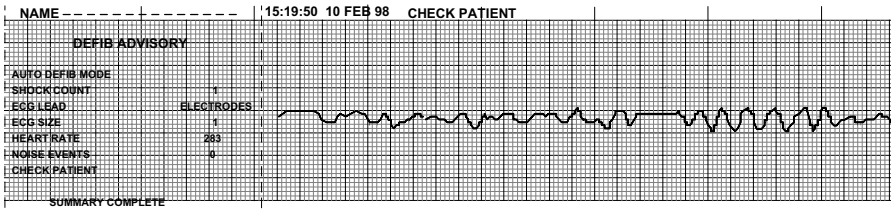
Heart Rate Alarm Activated Format

Summary Report records 6 seconds of pre-alarm patient ECG. Also recorded are the ECG lead, ECG size, patient's heart rate, time, and date. If the pacer is on during this event the pacing rate and pacing current are also recorded.



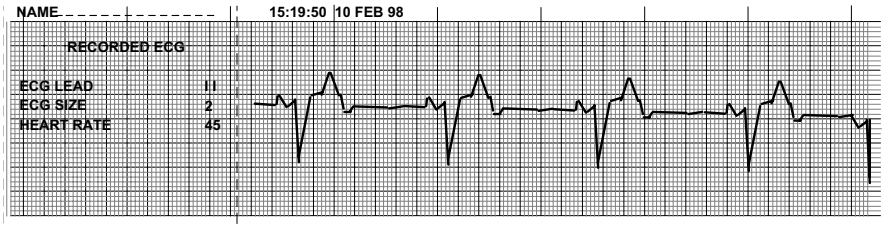
VF Alarm Activated (Refer to Section 8)

The summary report records (15) fifteen seconds of patient ECG data associated with each “VF” alarm. Also recorded are the shock count, ECG lead, ECG size, patient’s heart rate, and noise events.



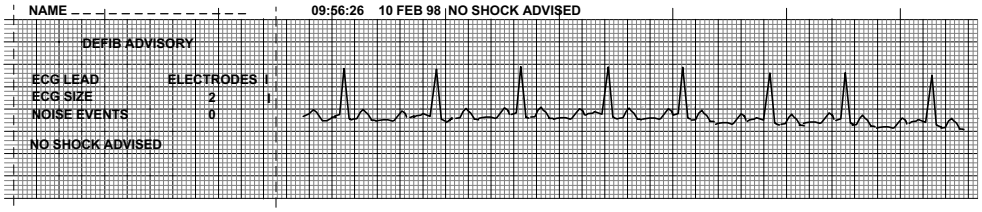
Recorder On Format

Summary Report records 6 seconds of patient ECG prior to turning on the recorder. Also recorded are the ECG lead, ECG size, patient's heart rate, time, and date. If the pacer is on during this event the pacing rate and pacing current are also recorded. If async pace is active, the annotation “ASYNC PACE” is recorded. AED units will additionally include shock count and AED mode annotations.



Analyze Format

The summary report records six seconds of pre analysis ECG and 9 seconds of ECG recorded during the ECG analysis interval with the annotation "SHOCK ADVISED" or "NO SHOCK ADVISED". AED units will additionally include shock count and AED mode annotations.



Manual Mode Activated

AED versions of the **M-Series** that are equipped with manual mode capabilities will record a "MANUAL MODE STARTED" event within Summary Report whenever the device is switched from the AED (Default) mode to the Manual operating mode.

The following annotations may also be printed at the top of the Analyze Format printout:

Annotation	Description
1. POOR PAD CONTACT:	The MFE Pads are detected as having poor connection.
2. ANALYSIS HALTED:	The ECG analysis is halted due to either the **ANALYZE** button being pushed or a fault condition.
3. NOISY ECG:	Excessive noise is detected.
4. SHOCK ADVISED:	Shockable rhythm has been detected at the end of user-initiated ECG analysis.
5. NO SHOCK ADVISED	No shockable rhythm has been detected at the end of user-initiated ECG analysis.
6. ECG TOO LARGE	The amplitude of the ECG signal is too large for proper rhythm analysis.

Printing a Report

To print the stored information, press the **SUMMARY** button below the screen display. Then press the corresponding softkey to print configuration settings, print chart, or print log.

The recorder will print all events currently in memory in chronological order. If the stripchart recorder is on or the defibrillator is charged, summary report printing is disabled. To stop printing a report, press the **RECORDER** button or turn the unit off. An unlimited number of copies of the report may be printed by simply pressing the **SUMMARY** button and corresponding print softkey again.

Pressing the **RECORDER** button while printing a summary report will cause the unit to stop printing the report. Press the **RECORDER** button again to begin printing an ECG trace. The stripchart recorder will run continuously until the button is pressed again.

Pressing the **SUMMARY** button and a corresponding print softkey while printing a report will cause the current report to stop printing and a new report to begin printing.

Printing is interrupted if a vital sign alarm occurs (i.e. HR, SpO2, etc.), the **ANALYZE** button is pressed, or the defibrillator is charged.

If the recorder is out of paper when the **SUMMARY** button and a corresponding print softkey are pressed, a “CHECK RECORDER” message will appear on the display. Load paper and press **SUMMARY** again to select the report to print.

Printing Part of a Report

If you want to print out only a portion of the Summary Report:

1. Press the **SUMMARY** button.
2. Press the **Print Chart** softkey.
3. Press the **Print Range** softkey.
4. Press **Prove. Event** or **Next Event** softkey to scroll through the events.
5. Press **Print** softkey.

The M Series unit prints the displayed event and all following events.

Adding Patient Name and ID# to a Report

To add patient name and identification number to the summary report:

1. Press **ID #** softkey.
2. Press **Prove Digit** or **Next Digit** softkey to select letter for patient name.
3. Press **Inc Digit** or **Dec. Digit** softkey to change value of letter.
   Repeat steps 2 and 3 until you have entered the patient’s entire name.
4. Press **Enter Name** softkey.
5. Press **Prove Digit** or **Next Digit** softkey to select digit or letter for identification number.
6. Press **Inc Digit** or **Dec. Digit** softkey to change value of digit.
   Repeat steps 5 and 6 until you have entered the patient’s entire identification number.
7. Press **Enter ID and Return** softkey.

Note: Patient name cannot be retrospectively added to summary report events already stored in memory. The patient name is only stored with summary events saved after the patient name has been entered.

Printing an Incident Log

An incident log is an abbreviated list of all major events recorded in the summary report. You can print out an incident log that includes the time of occurrence of the following events:

- M Series unit powered on.
- Defibrillation advisory messages (for example, CHECK PATIENT and SHOCK ADVISED).
- Defibrillation shocks (including energy level).
- Pacer mode activated.
- Manual mode started (AED only).
- Alarms triggered.
- Code markers.
- 12 Lead analysis initiated.
- 12 Lead data transmission.
- Recorder turned on.
- NIBP measurements activated.

In addition, the incident log lists the following:

- Report start time (time when summary report memory was erased).
- Last event time (time of last event in memory).
- Total number of shocks.
- Total pacer time.
- System serial number.
- Device identification number.

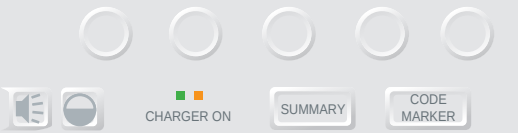
To print an incident log:

1. Press the **SUMMARY** button.
2. Press the **Print Log** softkey.

   The **M Series** unit prints incident log.

Erasing Summary Report Memory

To erase all stored information, press and hold the **SUMMARY** button for approximately 4 seconds. Then press the corresponding softkey to erase summary, erase trend, or erase all event reports. An "ERASING REPORT" message will appear on the display.



Turning the unit off for more than fifteen (15) minutes, unless configured otherwise, will also erase summary and trend report memory.

SECTION 3
MANUAL DEFIBRILLATION

Paddles are a defibrillation protected Type BF patient connection.

ECG leads are a defibrillation protected Type CF patient connection.

Emergency Defibrillation Procedure with Paddles

WARNING

- To avoid risk of electrical shock, do not allow electrolyte gel to accumulate on hands or paddle handles.
- When defibrillating with paddles use your thumbs to operate the SHOCK buttons in order to avoid inadvertent operator shock. No portion of the hand should be near the paddle plates.

Determine Patient Condition Following Medical Protocols

Verify:

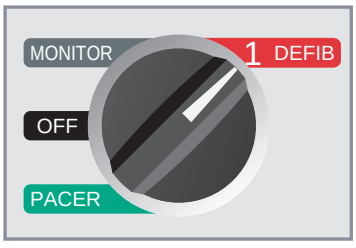
- Unconsciousness
- Absence of breathing
- Absence of pulse

Begin CPR following medical protocols

Request additional assistance.

1 Select DEFIB

Turn the **SELECTOR SWITCH** to **DEFIB.** The unit automatically defaults to 200 Joules or the first shock energy selection pre-configured by the user.



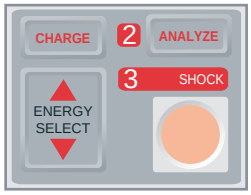
Note: Defibrillator "PADDLES" are selected as the ECG source when the instrument is turned to MONITOR or DEFIB and paddles are connected to the Multi-Function cable.

Energy Select

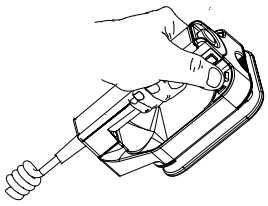
Observe the display and verify the selected energy is appropriate. To change the energy setting use either pair of up-down arrow buttons. One pair is located on the front panel of the unit, the other pair is located on the sternum paddle. The selected energy level will be shown as "DEFIB XXXJ SEL." on the display.

If the M Series unit is configured to do so, it automatically sets the energy to the pre-configured Energy Level: Shock 1, 2, 3 setting at power-up and after each of the first two shocks. The "ENERGY INCREMENTED" message displays when this occurs. Manually changing the energy level outside the pre-programmed sequence

and delivering a shock disables this function. This function is disabled when internal spoons are connected. See the M Series Configuration Guide for more details.



or



Note: Neonatal and Pediatric defibrillator energy levels should be set based on site-specific clinical protocols.

Prepare Paddles

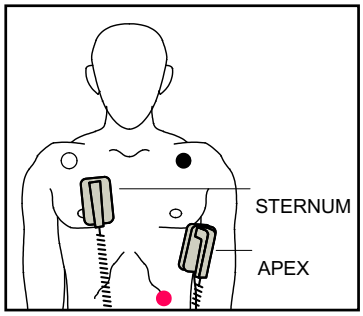
Remove the paddles from their holders by grasping the handles and pressing down on the paddle release latch located above each paddle. Apply a liberal amount of electrolyte gel to the electrode surface of each paddle. (Use of electrode gel patches can be substituted for gel applied to paddle surfaces.)

Rub the electrode surfaces together to evenly distribute the applied gel.

Apply Paddles to Chest

Apply the paddles firmly to the anterior wall of the chest. Place the "Sternum" paddle to the right (patient's right) of the patient's sternum, just below the clavicle.

Place the "Apex" paddle on the chest wall, just below and to the left of the patient's left nipple, along the anterior-axillary line.



Rub the paddles against the skin to maximize the paddle-to-patient contact

WARNING

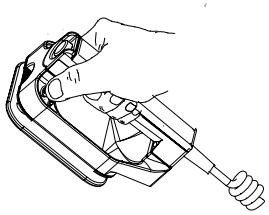
- Do not permit gel to accumulate between the paddle electrodes on the chest wall (gel bridge). This could cause burns and reduce the amount of energy delivered to the heart.
- If using defibrillator gel pads make sure that the size of the pad is large enough to cover the entire paddle electrode area.

The paddles may be used for ECG monitoring in emergency situations when time does not allow connection of standard ECG monitoring electrodes. The unit automatically pre-selects "PADDLES" when it is initially turned on and paddles are connected to the Multi-Function cable.

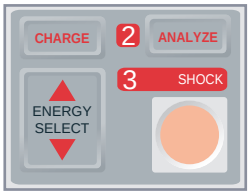
If an ECG cable and ECG electrodes are in use, press the **LEAD** button to select the desired ECG lead configuration - I, II, III or PADDLES (also aVR, aVF, aVL and V if the unit has been so configured).

2 Charge Defibrillator

Press the **CHARGE** button on the front panel or on the apex paddle handle.



or



If both **SHOCK** buttons on the paddles are depressed when the **CHARGE** button is activated, the device will not charge and a "RELEASE SHOCK BUTTON" or other message will appear on the display.

To increase or decrease the selected energy after the **CHARGE** button has been pressed, use the defibrillator energy select buttons on either the sternum paddle or defibrillator front panel.

CAUTION

- Changing the selected energy while the unit is charging or charged will cause the defibrillator to disarm itself. Press the **CHARGE** button again to charge the unit.

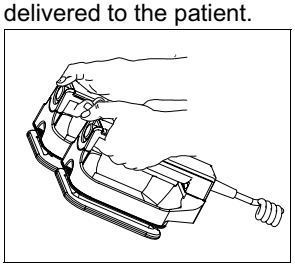
After charging to the selected energy, the charge indicator on the apex paddle will light. A distinctive charge ready (continuous) tone sounds and the energy ready "DEFIB XXXJ READY" message will be displayed. The defibrillator is now ready.

3 Deliver SHOCK

WARNING

- Warn all persons in attendance of the patient to STAND CLEAR prior to defibrillator discharge.
- Do not touch the bed, patient, or any equipment connected to the patient during defibrillation. A severe shock can result. Do not allow exposed portions of the patient's body to come in contact with metal objects, such as a bed frame, as unwanted pathways for defibrillation current may result.

Using your thumbs, simultaneously press and hold both **SHOCK** buttons (one on each paddle) until energy is delivered to the patient.



Once energy is delivered, the display will simultaneously show “XXXJ DELIVERED” and “DEFIB XXXJ SEL”. After approximately 5 seconds the “XXXJ DELIVERED” message will disappear and the “DEFIB XXXJ SEL” message remains to indicate the selected energy level.

CAUTION

- Only use thumbs to depress the **SHOCK** buttons. Failure to do so could result in the inadvertent depression of the **ENERGY SELECT** buttons, causing the defibrillator to disarm itself.

Note: If the defibrillator is not discharged within 60 seconds after reaching the selected energy level, the unit automatically disarms itself.

During the ten seconds prior to disarming, the charge ready tone will beep intermittently. The charge ready tone will then stop, the charge indicator light will go off, and the monitor message will change to “DEFIB XXXJ SEL.” Press the **CHARGE** button to recharge the unit.

Paddle Cleaning

Paddle plates and handles must be thoroughly cleaned after each use. See the **General Maintenance** Section for correct cleaning procedure.

Emergency Defibrillation Procedure with MFE Pads

Paddles are a defibrillation protected Type BF patient connection.

ECG leads are a defibrillation protected Type CF patient connection

Determine Patient Condition Following Medical Protocols

Verify:

- Unconsciousness
- Absence of breathing
- Absence of pulse

Begin CPR following medical protocols

Request additional assistance.

Prepare Patient

Remove all clothing covering the patient's chest. Dry chest if necessary. If the patient has excessive chest hair, clip it to ensure proper adhesion of electrodes.

Attach the Multi-Function Electrode (MFE) Pads according to instructions on the electrode packaging.

Ensure that all MFE Pads are making good contact with the patient's skin and are not covering any part of the ECG electrodes.

Connect MFE Pads to the multi-function cable if not preconnected.

The messages "CHECK PADS" and "POOR PAD CONTACT" will be alternately displayed and energy will not be delivered if the MFE Pads are not making good contact with the patient

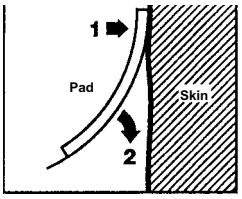
The message "DEFIB PAD SHORT" will be displayed to indicate that a short circuit between MFE Pads may exist.

MFE Pad Application

WARNING

- Poor adherence and/or air under the MFE Pads can lead to the possibility of arcing and skin burns.

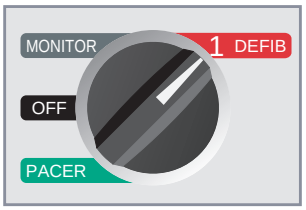
1. Apply one edge of the pad securely to the patient.
2. "Roll" the pad smoothly from that edge to the other being careful not to trap any air pockets between the gel and skin.



Note: If it is not possible to place the "BACK" MFE Pad on the patient's back, the MFE Pad should be placed in the standard apex-sternum configuration. Effective defibrillation will result, but pacing with the device will usually be less effective.

1 Select DEFIB

Turn the **SELECTOR SWITCH** to **DEFIB.** The unit automatically defaults to 200 Joules or the first shock energy selection pre-configured by the user.



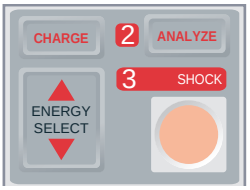
Note: Multi-function "PADS" are selected as the ECG source whenever the instrument is turned to MONITOR or DEFIB and paddles are not connected to the Multi-Function cable. You may select any of the other ECG lead configurations - I, II, III (also aVR, aVF, aVL and V) if the unit has been so configured and ECG cable/electrodes are in use.

Energy Select

Observe the display and verify the selected energy is appropriate. To change the energy setting use either pair of up-down arrow buttons. One pair is located on the front panel of the unit, the other pair is located on the sternum paddle. The selected energy level will be shown as “DEFIB XXXJ SEL.” on the display.

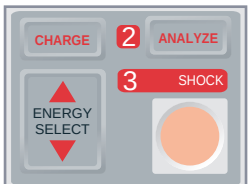
If the M Series unit is configured to do so, it automatically sets the energy to the pre-configured Energy Level: Shock 1, 2, 3 setting at power-up and after each of the first two shocks. The “ENERGY INCREMENTED” message displays when this occurs. Manually changing the energy level outside the pre-programmed sequence and delivering a shock disables this function. This function is disabled when internal spoons are connected. See the M Series Configuration Guide for more details.

Note: Neonatal and Pediatric defibrillator energy levels should be set based on site-specific clinical protocols.



2 Charge Defibrillator

Press the CHARGE button on the front panel.



To increase or decrease the selected energy after the **CHARGE** button has been pressed, use the defibrillator energy select buttons on the front panel.

CAUTION

- Changing the selected energy while the unit is charging or charged will cause the defibrillator to disarm itself. Press the **CHARGE** button again to charge the unit.

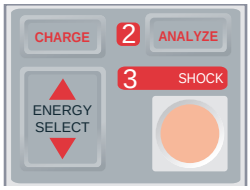
After charging to the selected energy, the **SHOCK** button on the front panel will light. A distinctive charge ready (continuous) tone sounds and the energy ready “DEFIB XXXJ READY” message will be displayed. The defibrillator is now ready.

3 Deliver SHOCK

WARNING

- Warn all persons in attendance of the patient to STAND CLEAR prior to defibrillator discharge.
- Do not touch the bed, patient, or any equipment connected to the patient during defibrillation. A severe shock can result. Do not allow exposed portions of the patient's body to come in contact with metal objects, such as a bed frame, as unwanted pathways for defibrillation current may result.

Press and hold the **SHOCK** button on the front panel until energy is delivered to the patient.



Once energy is delivered, the display will simultaneously show “XXXJ DELIVERED” and “DEFIB XXXJ SEL”. After approximately 5 seconds the “XXXJ DELIVERED” message will disappear and the “DEFIB XXXJ SEL” message remains to indicate the selected energy level.

Note: If the defibrillator is not discharged within 60 seconds after reaching the selected energy level, the unit will automatically disarm itself.

During the ten seconds prior to disarming, the charge ready tone will beep intermittently. The charge ready tone will then stop, the **SHOCK** button light will go off, and the displayed message will change to “DEFIB XXXJ SEL.” Press the **CHARGE** button to recharge the unit.

Open Chest Defibrillation with Internal Handles and Electrodes

ZOLL Autoclavable Internal Handles are designed for use with a manually operated ZOLL defibrillator and internal defibrillation electrodes to defibrillate the heart during open chest surgical procedures.

When used with a ZOLL defibrillator equipped with an advisory or ECG analysis feature, the ZOLL Autoclavable Internal Handles allow the defibrillator to operate only as a manual device.

Connection of the ZOLL Internal Handle Sets to the defibrillator automatically causes the defibrillator to limit its energy output to a maximum of 50 joules.

Refer to the Autoclavable Internal Handle and Electrode Operator's Guide for step by step open chest defibrillation procedure and important cleaning and sterilization information.

Troubleshooting

If your M Series unit does not function as expected, see the Defibrillator Troubleshooting section starting on page 11-5.

SECTION 4
ADVISORY DEFIBRILLATION

When Multi-function Electrode (MFE) Pads are used the patient connection is considered to be defibrillation protected Type BF.

Advisory Defibrillation

WARNING

- Do not use the unit's Advisory function on patients under 8 years of age.

The device can identify shockable rhythms using its built in ECG analysis capability when using MFE Pads to monitor ECG and defibrillate. The operator must read the advisory messages, charge the defibrillator to the user selected or preconfigured energy level (if automatic charge is disabled), and deliver treatment to the patient when required by protocol and patient condition.

The Advisory function can only be activated when:

- MFE Pads are connected and selected as the ECG source
- MFE Pads are firmly attached to the patient to reduce any electrode noise or artifact

and

- **SELECTOR SWITCH** is turned to **DEFIB.**

Determine Patient Condition Following Medical Protocols

Verify:

- Unconsciousness
- Absence of breathing
- Absence of pulse

Begin CPR following medical protocols

Request additional assistance.

Prepare Patient

Remove all clothing covering the patient's chest. Dry chest if necessary. If the patient has excessive chest hair, clip it to ensure proper adhesion of electrodes.

Attach the MFE Pads according to instructions on the electrode packaging.

Ensure that all MFE Pads are making good contact with the patient's skin and are not covering any part of the ECG electrodes.

Connect MFE Pads to the multi-function cable if not preconnected.

The messages "CHECK PADS" and "POOR PAD CONTACT" will be alternately displayed and energy will not be delivered if the MFE Pads are not making good contact with the patient.

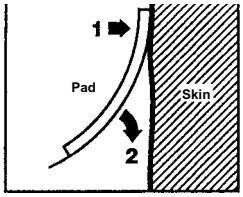
The message "DEFIB PAD SHORT" will be displayed to indicate that a short circuit between MFE Pads may exist.

MFE Pad Application

WARNING

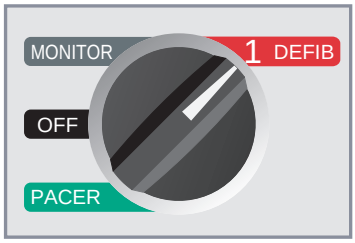
- Poor adherence and/or air under the MFE Pads can lead to the possibility of arcing and skin burns.

1. Apply one edge of the pad securely to the patient.
2. "Roll" the pad smoothly from that edge to the other being careful not to trap any air pockets between the gel and skin.



Note: If it is not possible to place the "BACK" MFE Pad on the patient's back, the MFE Pad should be placed in the standard apex-sternum configuration. Effective defibrillation will result, but pacing with the device will usually be less effective.

1 Select DEFIB



The unit displays "DEFIB 200J SEL" on the monitor until the **ANALYZE** button is depressed by the operator.

Energy Select

Shock number 1 is set at 200 joules, shock 2 is set at 200 joules and shock 3 and up is set at 360 joules (default setting). If medical protocols allow, the operator may select a different energy level using the energy select up (▲) and down (▼) arrow buttons. The new energy setting will display on the monitor.

Manually changing the energy level outside the pre-programmed Shock 1, 2, 3 sequence and delivering a shock disables automatic energy escalation. See the Energy Level: Shock 1, 2, 3 section of the M Series Configuration Guide for more details.

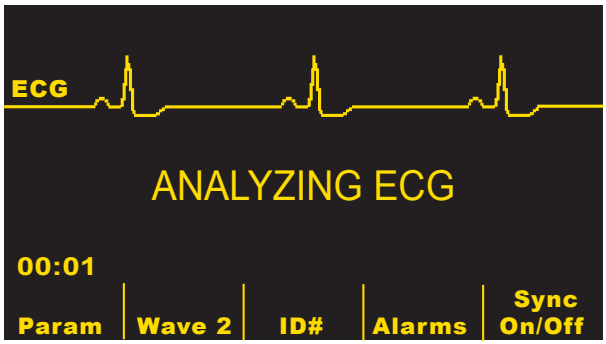
2 Press ANALYZE Button

WARNING

- A patient must be motionless during ECG analysis. Do not touch the patient during analysis. Cease all movement via stretcher or vehicle before analyzing the ECG.

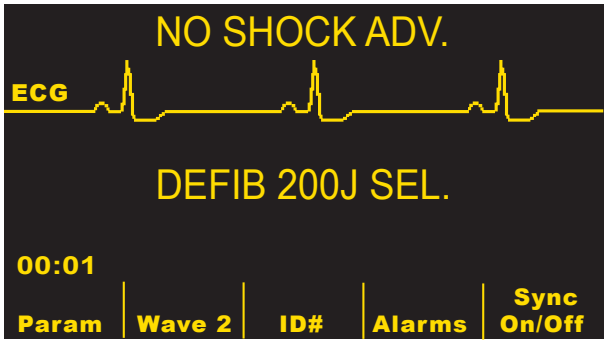
Press the **ANALYZE** button to begin analysis of the patient's ECG rhythm and to detect the presence of any shockable rhythms.

An "ANALYZING ECG" message will be displayed for approximately 9 to 12 seconds while the patient's ECG is analyzed.



Once the analysis is completed, the unit indicates whether or not a shock is advised.

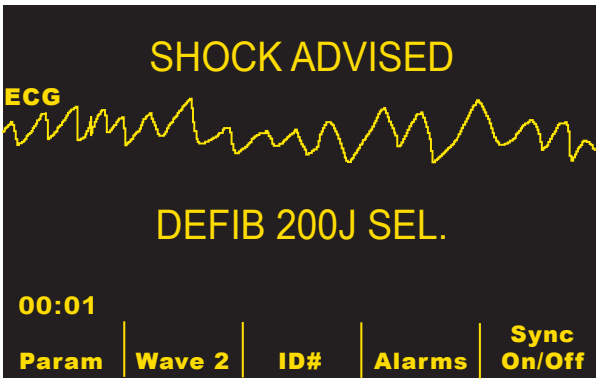
When a non-shockable rhythm is detected the message "NO SHOCK ADV." will be displayed.



Follow local protocols to continue CPR or other cardiopulmonary life support and re-analyze the ECG at appropriate intervals.

When a shockable rhythm is detected (Ventricular Fibrillation or Tachycardia with heart rate > 150), units with the automatic charge option enabled will automatically charge the defibrillator to the preconfigured or user selected energy setting.

Units with the automatic charge option disabled will alternately display the messages "SHOCK ADVISED" and "PRESS CHARGE" when a shockable rhythm is detected.

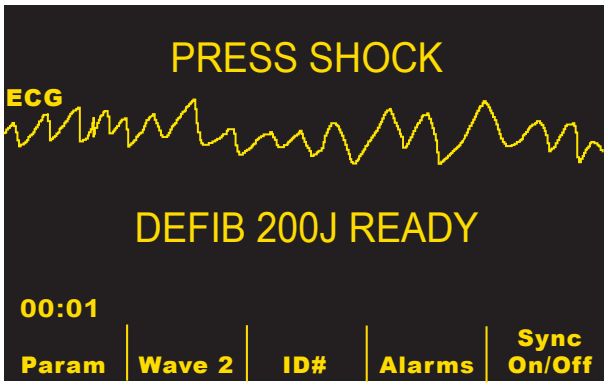


3 Press SHOCK

WARNING

- Warn all persons in attendance of the patient to STAND CLEAR prior to defibrillator discharge.
- Do not touch the bed, patient, or any equipment connected to the patient during defibrillation. A severe shock can result. Do not allow exposed portions of the patient's body to come in contact with metal objects, such as a bed frame, as unwanted pathways for defibrillation current may result.

Once the unit has charged to the selected energy, the **SHOCK** button will illuminate and the “PRESS SHOCK” message will be displayed. Simultaneously, the monitor displays the energy level to which the defibrillator has been charged, “DEFIB XXXJ READY”.



A continuous tone will sound for 50 seconds, followed by an intermittent beeping for 10 seconds. The shock must be delivered within this 60 second interval or the defibrillator will disarm itself.

Press and hold the illuminated **SHOCK** button on the front panel until energy is delivered to the patient. An “XXXJ DELIVERED” message will appear on the display for approximately 5 seconds.

Observe the patient or ECG response to be certain that the shock has been delivered.

After the energy is delivered to the patient, the display returns to DEFIB XXX J SEL.

Repeat Analysis

Press the **ANALYZE** button to restart an ECG analysis and determine if additional shocks are required.

Note: Reanalysis of the ECG rhythm, either manually or automatically (see M Series Configuration Guide), is inhibited for 3 seconds after a shock.

Continue Patient Care

Continue patient care according to medical protocols.

Advisory Function Messages

SELECT DEFIB MODE

This message will appear if the **ANALYZE** button is pressed but the unit is not in the **DEFIB** mode. Move the **SELECTOR SWITCH** to **DEFIB** to enable the defibrillator and advisory capability.

SELECT PADS

Displayed if the **ANALYZE** button is pressed and the device is being operated in any lead configuration other than “PADS”. Press **LEAD** button until “PADS” are selected.

DISABLE SYNC

Displayed if the **ANALYZE** button is pressed and the device is in SYNC DEFIB mode. The unit should be taken out of SYNC mode by pressing the **SYNC** softkey. Press the **ANALYZE** button again to initiate rhythm analysis on the patient.

Warning Messages

Warning messages prompt the operator to check the patient, the unit, the electrodes and/or connections.

WARNING

- The ECG Rhythm Analysis function does not warn the operator of patient asystole, as it is not a shockable rhythm.

NOISY ECG / RETRY ANALYSIS

A NOISY ECG message alternating with a RETRY ANALYSIS message is displayed for 5 seconds when the unit detects a noisy ECG signal. Check and adjust electrode placement and cable connections to help eliminate the noise source. Press the **ANALYZE** button again to begin ECG analysis.

ECG TOO LARGE / RETRY ANALYSIS

ECG TOO LARGE message will be displayed when the ECG signal is too large for proper rhythm analysis. Press the **ANALYZE** button again to begin ECG analysis.

CHECK PATIENT

The unit detects a shockable rhythm during continuous background ECG analysis without initiating an analysis (i.e., Smart Alarms™). The prompt is given when the heart rate alarms are enabled and the unit detects a shockable rhythm or if the rhythm goes from non-shockable to shockable. The screen message persists as long as a shockable rhythm is being detected. Press the **ANALYZE** button to begin ECG analysis.

Note: This CHECK PATIENT analysis function operates continuously when heart rate alarms are enabled and does not require depression of the ANALYZE button for operation.

CHECK PADS / POOR PAD CONTACT

The Multi-Function Pads are no longer properly attached to the patient or the cable connections have become loose.

Check that the MFE Pads are making good contact with the patient's skin and that the cables are all securely connected. This voice prompt will not sound if the MFE Pads were not previously connected to the patient.

Troubleshooting

If your M Series unit does not function as expected, see the Defibrillator Troubleshooting section starting on page 11-5.

SECTION 5

AUTOMATED EXTERNAL DEFIBRILLATOR (AED) OPERATION

When Multi-function Electrode (MFE) Pads are used the patient connection is considered to be defibrillation protected Type BF.

Introduction

WARNING

- Do not use the unit's Advisory function on patients under 8 years of age.

This section describes the recommended method of operation. If your local protocol requires a different procedure, follow that protocol.

The unit is capable of analyzing a patient's ECG rhythm in two different ways. The first mode of analyzing is always active in the background of the semi-automatic mode (continuous analysis) when MFE Pads or ECG cable and electrodes are in use. The other mode of analyzing is user activated analysis, initiated by pressing the **ANALYZE** button.

User activated analysis of a patient's ECG can only be performed when:

- MFE Pads are connected.
- MFE Pads are firmly attached to the patient to reduce any electrode noise or artifact.
- **SELECTOR SWITCH** is turned to **ON**.

In semi-automatic mode, pressing the **ANALYZE** button causes the unit to begin an analysis of the patient's ECG in order to determine if a shockable rhythm is present.

This analysis consists of three consecutive 3-second ECG rhythm analyses. If at least two of the three analyses determine that the patient has a shockable rhythm, the unit will automatically charge to the pre-configured energy level and prompt the operator to shock the patient. If two or more of the three 3-second ECG analyses do not detect a shockable rhythm, the unit will alert the operator that no shock is advised.

Following each shock, the continuous analysis function resumes operation and will issue a "CHECK PATIENT" message and audio prompt if a shockable rhythm is detected. (Continuous analysis runs on a sliding 12 second window of ECG data, producing a result every 3 seconds. If three (3) out of four (4) 3-second segments are shockable, the "CHECK PATIENT" message is issued.)

The "CHECK PATIENT" message and voice prompt will be inhibited for 70 seconds, however, following the completion of a user activated analysis or discharge.

AED Semi-Automatic Operation

Determine Patient Condition Following Medical Protocols

Verify:

- Unconsciousness
- Absence of breathing
- Absence of pulse

Begin CPR following medical protocols

Request additional assistance.

Prepare Patient

Remove all clothing covering the patient's chest. Dry chest if necessary. If the patient has excessive chest hair, clip it to ensure proper adhesion of electrodes.

Attach the MFE Pads according to instructions on the electrode packaging.

Ensure that all MFE Pads are making good contact with the patient's skin and are not covering any part of the ECG electrodes.

Connect MFE Pads to the multi-function cable if not preconnected.

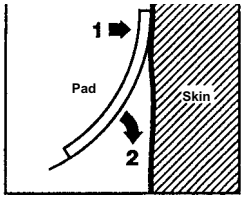
The message "CHECK PADS" will be displayed and energy will not be delivered if the MFE Pads are not making good contact with the patient or if a short circuit exists between the MFE pads.

MFE Pad Application

WARNING

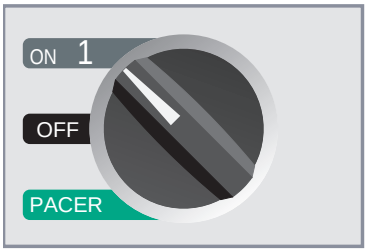
- Poor adherence and/or air under the MFE Pads can lead to the possibility of arcing and skin burns.

1. Apply one edge of the pad securely to the patient.
2. "Roll" the pad smoothly from that edge to the other being careful not to trap any air pockets between the gel and skin.



Note: If it is not possible to place the "BACK" MFE Pad on the patient's back, the MFE Pad should be placed in the standard apex-sternum configuration. Effective defibrillation will result, but pacing with the device will usually be less effective.

1 Select ON



The unit will beep 4 times to indicate that it has passed the power-on self-test. If the audio recorder is present, the unit will begin recording audio data immediately.

If no MFE pads or ECG electrodes have been attached to the patient and connected to the M Series, an "ATTACH PADS" message and voice prompt will be issued.

Energy Select

For non-Biphasic units shock number 1 is set at 200 joules, shock 2 is set at 200 joules and shock 3 and up is set at 360 joules (default setting). For Biphasic units shock number 1 is set at 120 joules, shock 2 is set at 120 joules and shock 3 and up is set at 200 joules. If medical protocols allow, the operator may select a different preconfigured energy level using the energy select up ▲ and down ▼ arrow buttons. The new energy setting will display on the monitor.

2 Press ANALYZE Button

WARNING

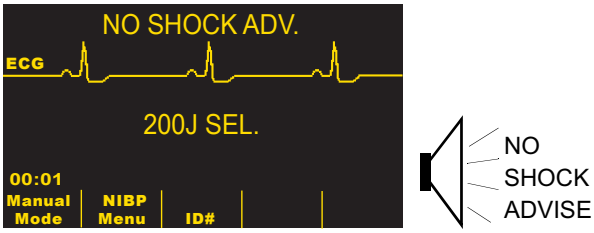
- Do not use the unit in semiautomatic mode during patient movement. A patient must be motionless during ECG analysis. Do not touch the patient during analysis. Cease all movement via stretcher or vehicle before analyzing the ECG. If using the device in an emergency vehicle, bring the vehicle to a halt before using in semiautomatic mode.

Press the **ANALYZE** button to begin analysis of the patient's ECG rhythm. The device announces and displays a "STAND CLEAR" message. If MFE pads have not been properly connected to the patient, a "USE PADS" message will be displayed and analysis will be inhibited.

An "ANALYZING ECG" message is then displayed for up to 12 seconds while the patient's ECG is analyzed.

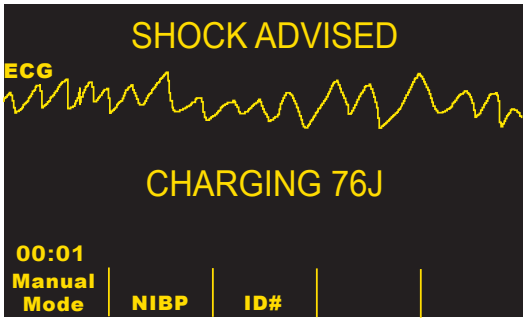
Once the analysis is completed, the unit indicates whether or not a shock is advised.

When a non-shockable rhythm is detected the unit displays a "NO SHOCK ADV." message.



Immediately check pulse and breathing and resume other treatment per protocol.If the patient's rhythm is

shockable the unit will display a “SHOCK ADVISED” message.



The defibrillator will begin charging automatically to the pre-configured energy setting and display a “CHARGING” message.

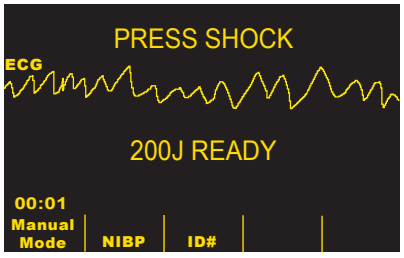
When charging is completed the monitor displays the energy level to which the defibrillator has been charged, “XXXJ READY”.

3 Press SHOCK

WARNING

- Warn all persons in attendance of the patient to STAND CLEAR prior to defibrillator discharge.
- Do not touch the bed, patient, or any equipment connected to the patient during defibrillation. A severe shock can result. Do not allow exposed portions of the patient's body to come in contact with metal objects, such as a bed frame, as unwanted pathways for defibrillation current may result.

Once the unit has charged to the selected energy, the **SHOCK** button will illuminate and the “PRESS SHOCK” message will be announced and displayed.

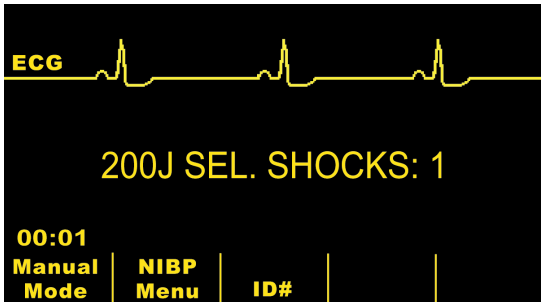


A continuous tone will sound for 10 seconds, followed by an intermittent beeping for 5 seconds. The shock must be delivered within this 15 second interval or the defibrillator will disarm itself.

Press and hold the illuminated **SHOCK** button on the front panel until energy is delivered to the patient.

Observe the patient or ECG response to be certain that the shock has been delivered.

After the energy is delivered to the patient, the display returns to XXX J SEL. SHOCKS: 1, indicating the number of shocks administered to the patient.



Repeat Analysis

Press the **ANALYZE** button to restart an ECG analysis and determine if additional shocks are required.

Note: Reanalysis of the ECG rhythm, either manually or automatically (see the M Series Configuration Guide), is inhibited for 3 seconds after a shock.

Continue Patient Care

Continue patient care according to medical protocols.

Operating Messages

The unit uses both audio and visual prompts to present critical information to operators. The following information describes the unit default configuration. If your device has been custom configured some of the information may be different.

There are nine (9) voice prompts used in semi-automatic mode. These prompts are accompanied by a message displayed on the monitor. The voice prompts are given only once, but the monitor continues to display the message until new action is taken by the operator or the device status changes.

The unit also provides a beeper tone to indicate unit status. Four beeps immediately after turning the unit on signifies the self diagnostics are complete and unit is ready for operation. Additional tone signals are described later.

The display has fields where messages appear. The messages that appear depend upon the functions the unit is performing, the mode selected, and the ECG information from the patient.

The unit will alternately display two different messages in the same field of the display when two conditions are detected at the same time. For example, a “LOW BATTERY” message may alternately display on the same line of the monitor as the “CHECK PADS” message.

The upper portion of the display indicates some operator prompts and error messages. The center portion of the display indicates approximately 4 seconds of ECG trace.

The lower portion of the display indicates the energy levels selected, the number of shocks delivered during the incident, the elapsed time (if enabled), and softkey function labels. Additional unit status information is also displayed on the monitor.

Audio and Display Messages

Described below are the display messages and voice prompts that can occur during semi-automatic operation.

ATTACH PADS

If the unit is powered on without the Multi Function Pads or ECG leads attached the "ATTACH PADS" message will be announced and displayed.

PRESS ANALYZE

The unit will display a "PRESS ANALYZE" prompt under the following conditions:

- after the unit is charged, but no shock was delivered.
- 70 seconds after completion of an analysis with NO SHOCK ADVISED outcome, if the unit is configured to Auto Analyze 3 Times.
- 70 seconds after delivery of the third shock in three-analyses sequence, if the unit is configured to Auto Analyze 3 Times.

ANALYZING ECG/STAND CLEAR

These messages appear after pressing the **ANALYZE** button. They indicate that an active ECG analysis is in progress.

ECG TOO LARGE/RETRY ANALYSIS

ECG TOO LARGE message will be displayed when the ECG signal is too large for proper rhythm analysis. Press the **ANALYZE** button again to begin ECG analysis.

CHARGING XXXJ

ECG analysis is still in progress and a potentially shockable rhythm has been detected. The current charge level and a message that the unit is charging are displayed.

SHOCK ADVISED/CHARGING

ECG analysis has determined that a shockable rhythm exists and defibrillation is advised. The selected charge level has not yet been reached. The current charge level and a message that the unit is charging are displayed.

SHOCK ADVISED/XXXJ READY

ECG analysis has determined that a shockable ECG rhythm is present and the selected energy is ready to be delivered.

PRESS SHOCK

ECG analysis has determined that a shock is advised. The selected energy is ready to be delivered and a "PRESS SHOCK" message will be displayed and announced. Pressing and holding the **SHOCK** button on the front panel delivers the shock to the patient.

RELEASE SHOCK

If the SHOCK button is pressed during charging (before the DEFIB XXX J READY message), a "RELEASE SHOCK" message will be displayed and the unit will beep. If the SHOCK button remains depressed for 15 seconds after the ready tone begins the unit will disarm itself. If the SHOCK button is released before 15 seconds has elapsed the "PRESS SHOCK" message will appear and the shock can be delivered.

SHOCKS: XX

Indicates the number of shocks that have been delivered by the unit since Power On. Resets to 0 after the unit has been off for more than 10 seconds. (This allows replacing a battery without resetting the shock count.)

NO SHOCK ADVISED

When ECG analysis determines that a non-shockable rhythm is detected this message will appear and continue for 10 seconds following completion of the analysis.

Press the **ANALYZE** button to start another ECG analysis

CHECK PADS

MFE pads or MFC cable has become disconnected from the patient.

CHECK PATIENT/PRESS ANALYZE

Background ECG Analysis has detected a shockable ECG rhythm. Press Analyze to analyze ECG and if needed begin defib charging.

ELAPSED TIME

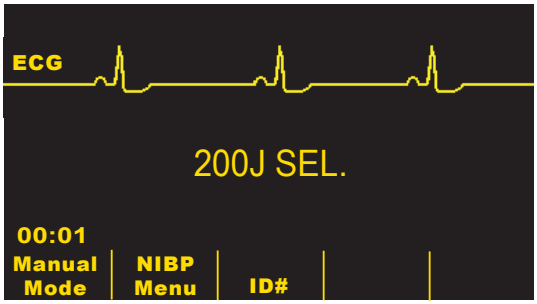
When enabled, this feature indicates the elapsed time since the unit was first turned on. It is displayed in the lower left corner. The elapsed time is displayed in MM:SS format up to 99:59. If the unit is on for over 100 minutes, the elapsed time will roll over to 0. The elapsed time will be maintained for up to 10 seconds after power down. This will give the operator adequate time to change the unit's battery without resetting the elapsed time.

MONITOR

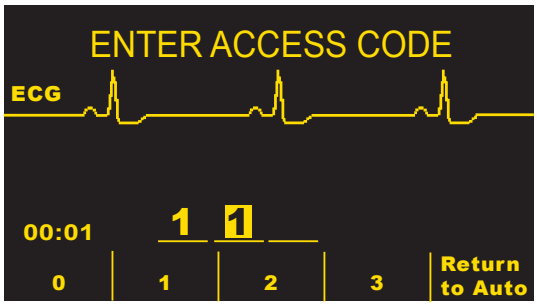
This message appears when the ECG cable is connected to its input connector, attached to the patient and the multi-function cable is not in use. The unit selects lead II and sets the ECG size automatically (Lead and ECG size cannot be changed by the operator).

AED Manual Mode Operation

Press the **Manual Mode** softkey on the front panel of the unit to enter the manual mode of operation.



Based on whether or not the device has been configured with an access code, one of the following two screens will be displayed.



In the above display, a three-digit access code must be entered to enter the manual mode (if configured). Press the individual softkey corresponding to the digit to be entered (each digit entered must be between 0 and 3). The highlight will automatically move to the next space. Repeat until the access code is entered correctly and the unit enters manual mode. If the **Return to Auto** softkey is pressed the unit will return to the semi-automatic mode of operation.

If the access code is not configured, the message “Confirm Manual Mode” and Confirm softkey will be displayed. Press the Confirm softkey to enter the manual mode of operation. If the Confirm softkey is not pressed within 5 seconds the unit will revert back to semi-automatic operation.

Refer to the “Manual Defibrillation”, “Advisory Defibrillation”, “Pacing”, and “ECG Monitoring” sections for the appropriate operation in manual mode.

AED Voice Prompts

The following is a list of the AED voice prompts:

- ATTACH PADS
- STAND CLEAR
- PRESS SHOCK
- CHECK PADS
- CHECK PULSE
- CHECK PATIENT
- IF NO PULSE, PERFORM CPR
- PRESS ANALYZE
- NO SHOCK ADVISED

Troubleshooting

If your M Series unit does not function as expected, see the Defibrillator Troubleshooting section starting on page 11-5.

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SECTION 6
SYNCHRONIZED CARDIOVERSION

Paddles are a defibrillation protected Type BF patient connection.

ECG leads are a defibrillation protected Type CF patient connection.

WARNING

- Synchronized cardioversion should only be attempted by skilled personnel trained in ACLS (Advanced Cardiac Life Support) and familiar with equipment operation. The precise cardiac arrhythmia must be determined before attempting defibrillation.
- Prior to attempting synchronized cardioversion, ensure that the ECG signal quality is sufficient to minimize risk of synchronizing on artifact

General Information

Certain arrhythmias, such as Ventricular Tachycardia (VT), atrial fibrillation, and atrial flutter, require synchronizing the defibrillator discharge with the ECG R-wave to avoid the induction of ventricular fibrillation. In this case, a synchronizing (SYNC) circuit within the instrument detects the patient's R-waves. When the **SHOCK** buttons are pressed and held, the unit will discharge with the next detected R-wave, thus avoiding the vulnerable T-wave segment of the cardiac cycle.

When placed in the SYNC mode the unit places markers above the ECG trace to indicate the points in the cardiac cycle where discharge will occur. The sync markers appear as arrows ("↓") above the ECG trace.

Verify that markers are clearly visible on the monitor and their location is appropriate and consistent from beat to beat. If necessary, use the **LEAD** button and **SIZE** button to establish settings that yield the best display.

The synchronized cardioversion procedure for MFE Pads is identical to that for paddles with the exception of the **SHOCK** button location.

Synchronized Cardioversion

Determine patient condition and provide care following medical protocols.

Prepare Patient

Remove all clothing covering the patient's chest. Dry chest if necessary. If the patient has excessive chest hair, clip it to ensure proper adhesion of electrodes.

Attach ECG electrodes.

A standard ECG cable and ECG electrodes are recommended for use during cardioversion. MFE Pads may be used as an ECG source and signal quality will be equal to that of standard leads except immediately following a discharge when there may be more noise due to muscle tremors, especially if a pad is not in complete contact with the skin.

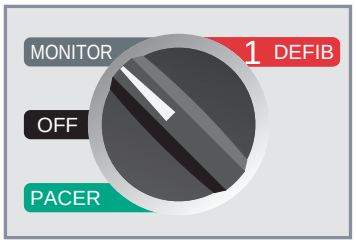
Apply MFE Pads to the patient according to the instructions on electrode packaging.

Ensure that the electrodes are in good contact with the patient's skin and are not covering any part of any other electrodes.

Connect MFE Pads to the multi-function cable unless preconnected.

If paddles are being used for synchronized cardioversion, refer to the **Emergency Defibrillation Procedure with Paddles** Section for preparing paddles, applying paddles, charging the defibrillator, and delivering a shock.

Turn Selector Switch to MONITOR



Press the **LEAD** button to select the desired ECG lead. The lead selected is displayed at the top of the screen.

Synchronized discharge with "PADDLES" as ECG source is discouraged since artifacts induced by moving the paddles may resemble an R-wave and trigger defibrillator discharge at the wrong time.

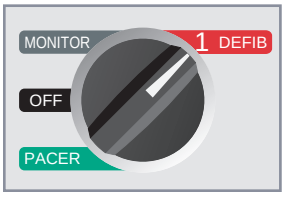
Standard ECG leads are recommended during cardioversion since they provide signal quality that is typically superior to that of paddles.

The use of standard ECG leads also provides the choice of multiple leads for ECG monitoring; Multi-function Pads provide only one.

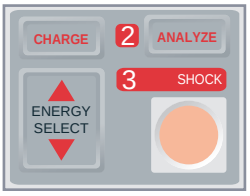
An "ECG LEAD OFF" condition will prevent synchronized discharge if leads are selected as ECG source. This does not prevent the use of the defibrillator. It simply prevents use in a synchronized manner.

1 Select DEFIB

Turn the **SELECTOR SWITCH** to **DEFIB**. Select the desired energy level using the up (▲) and down (▼) arrows on the front panel or sternum paddle.



and



Press SYNC softkey

The selected energy level is displayed on the monitor.

A SYNC marker ("↓") will appear on the monitor above each detected R-wave to indicate where discharge will occur.

Verify that markers are clearly visible on the monitor and their location is appropriate and consistent from beat to beat. If necessary, use the **LEAD** button and **SIZE** button to establish settings that yield the best display.

- A "SYNC XXXJ SEL." message will appear on the display. If "DEFIB XXXJ SEL." appears, press the **SYNC** button. Two quick beeps sound when the SYNC button is pushed.

Multi-function Pads may be used as an ECG source providing signal quality that is substantially equal to that of ECG leads.

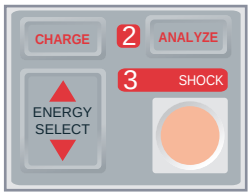
Unless otherwise configured, the unit automatically goes out of sync mode after each shock or if the Selector switch has been moved to PACER or OFF.

Press the SYNC button again to reactivate SYNC mode. Changing the selected energy does not cause the device to leave SYNC mode.

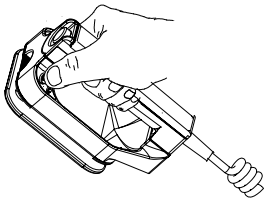
The unit can be configured to retain SYNC after defibrillation if desired.

2 Charge Defibrillator

Press the **CHARGE** button on the front panel or on the apex paddle handle.



or



CAUTION

- Changing the selected energy while the unit is charging or charged will cause the defibrillator to disarm itself. Press the **CHARGE** button again to charge the unit.

To abort charging and increase or decrease the selected energy after the **CHARGE** button has already been pressed, use the Energy Select buttons on either the sternum paddle or defibrillator front panel. Press the **CHARGE** button again to charge the unit.

After charging to the selected energy, the **SHOCK** button on the front panel or the charge indicator on the apex paddle will light. A distinctive audible tone will sound and the energy ready "SYNC XXXJ READY" message will be displayed.

The defibrillator is now ready.

3 Deliver SHOCK

WARNING

- Warn all persons in attendance of the patient to STAND CLEAR prior to defibrillator discharge.
- Verify that no one is in contact with the patient, monitoring cable or leads, bed rails, or any other potential current pathways.

Verify that the ECG waveform is stable and that a marker only appears with each R-wave.

Press and hold the illuminated, front panel **SHOCK** button or simultaneously press and hold both **SHOCK** buttons (one on each paddle) until energy is delivered to the patient. The defibrillator will discharge with the next detected R-wave.

Once energy is delivered, the display will simultaneously show “XXXJ DELIVERED” and “DEFIB XXXJ SEL”. After approximately 5 seconds the “XXXJ DELIVERED” message will disappear and the “DEFIB XXXJ SEL” message remains to indicate the selected energy level.

If additional countershocks are necessary, readjust the energy level as necessary, press the SYNC softkey and repeat. Note “SYNC XXXJ SEL” must be displayed prior to pressing the **CHARGE** button.

If it is necessary to disarm the charged defibrillator (if countershock is not needed), turn the selector switch to **MONITOR** or change the selected energy level. Any stored energy will be discharged internally by the defibrillator.

If the **ANALYZE** button is pressed while the unit is in SYNC mode, the unit will display “DISABLE SYNC” and disallow ECG rhythm analysis until the unit is taken out of SYNC mode.

If the defibrillator is not discharged within 60 seconds after reaching the selected energy level, it will automatically disarm itself. During the ten seconds prior to this internal disarm, the charge ready tone will beep intermittently. The charge ready tone will then stop and the defibrillator will remain in SYNC mode.

Troubleshooting

If your M Series unit does not function as expected, see the Defibrillator Troubleshooting section starting on page 11-5.

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SECTION 7

NON-INVASIVE TEMPORARY PACING (PACER VERSION ONLY)

Paddles are a defibrillation protected Type BF patient connection.

ECG leads are a defibrillation protected Type CF patient connection.

WARNING

- To avoid risk of electrical shock, do not touch the gelled area of the MFE Pads while pacing.
- MFE Pads should be replaced after 8 hours of continuous pacing (2 hours for Radiolucent *stat•padz*) to ensure maximum patient benefit.
- Prolonged pacing (in excess of 30 minutes), particularly in neonates or adults with severely restricted blood flow, may cause burns. Periodic inspection of the underlying skin is recommended.
- If the unit was not turned off and less than 10 minutes have elapsed since the pacing mode was last used, reactivating the pacer mode causes pacing to immediately resume at the previously selected mA and ppm settings.

Non-invasive Temporary Pacing

Some **M Series** products contain a VVI demand pacemaker—a safe and effective design for Noninvasive Temporary Pacemakers. Proper demand pacing requires a reliable high quality surface ECG signal.

Determine patient condition and provide care following medical protocols.

Prepare Patient

Remove all clothing covering the patient's chest. Dry chest if necessary.

1 Apply Electrodes and MFE Pads

Apply ECG electrodes (see the ECG MONITORING Section). Connect to ECG cable. Adjust ECG size and lead for a convenient waveform display. Verify proper R-wave detection. The heart-shaped symbol flashes with each R-wave when proper detection is taking place.

.

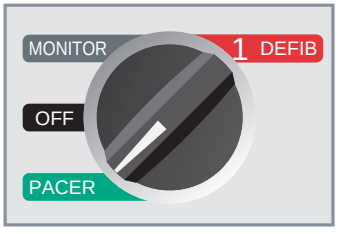
Apply MFE Pads

Apply MFE Pads according to the instructions on the pouch.

Ensure that all electrodes are making good contact with the patient's skin and are not covering any part of the other electrodes.

Connect MFE Pads to the Multi-Function cable.

2 Turn Selector Switch to PACER



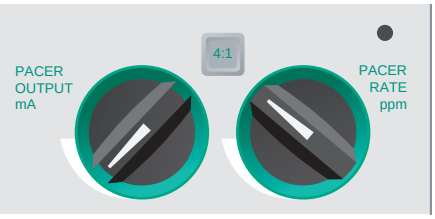
Set Pacer Output to 0 mA

If the unit has just been turned on, the **PACER OUTPUT** will automatically be set to 0 mA.

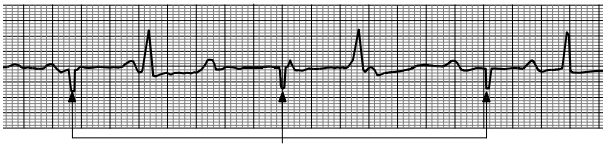
3 Set Pacer Rate

Set **PACER RATE** to a value 10-20 ppm higher than patient's intrinsic rate. If no intrinsic rate exists, use 100 ppm.

The pacer rate will increment or decrement by a value of 2 ppm on the display when the knob is turned.



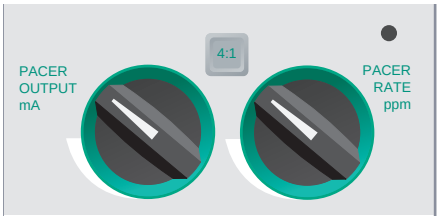
Observe the pacing stimulus marker on the display or stripchart (⊓⊔) and verify that it is well-positioned in diastole.



4 Set Pacer Output

Increase **PACER OUTPUT mA** until stimulation is effective (capture). Output mA value is displayed.

The pacer output will increment or decrement by a value of 2 mA on the display when the knob is turned.



Note: When the device is switched out of Pacer mode into Defib or Monitor mode and then switched back to Pacer mode, the Pacer settings will remain unchanged.

If the unit is turned off for more than 10 seconds, the pacer default settings will be restored.

5 Determine Capture

It is important to recognize when pacing stimulation has produced a ventricular response (capture). Determination of capture must be assessed both electrically and mechanically in order to assure appropriate circulatory support of the patient.

Electrical capture is determined by the presence of a widened QRS complex, the loss of any underlying intrinsic rhythm, and the appearance of an extended, and sometimes enlarged, T-wave.

WARNING

- Determination of electrical capture should only be performed by viewing the ECG on the screen with its ECG cable directly attached to the patient.
- Use of other ECG monitoring devices may provide misleading information due to the presence of pacer artifacts.

Mechanical capture is assessed by palpation of peripheral pulse.

In order to avoid mistaking muscular response to pacing stimuli for arterial pulsations the following are the ONLY recommended locations for palpating pulse during pacing:

- femoral artery
- right brachial or radial artery.

Ventricular response is normally characterized by suppression of the intrinsic QRS complex.

Effective Pacing

The following ECG tracings are typical of effective pacing:

- Negative R-wave and large T-waves.

- Widened positive QRS, which looks like an ectopic beat. A paced beat is by definition a ventricular ectopic beat.
- Inverted T-waves and the absence of P-waves.

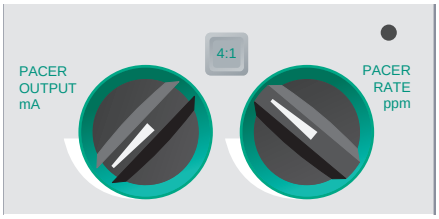
Changing ECG leads and size can sometimes be helpful in determining capture.

Note: Shape and size of the paced ECG waveforms can vary depending on the ECG lead configuration chosen; variation from patient to patient can be expected.

6 Determining Optimum Threshold

The ideal output current is the lowest value that will maintain capture. This is usually about 10% above threshold. Typical threshold currents are between 40 and 80 mA. Location of the MFE Pads will affect the current required to obtain ventricular capture. The MFE Pad placement that offers the most direct current pathway to the heart while avoiding large chest muscles will usually produce the lowest threshold. Low stimulation currents produce less skeletal muscle contraction and are better tolerated.

4:1 Mode



Pressing and holding the 4:1 button can be used to temporarily withhold pacing stimuli thereby allowing the operator to observe the patient's underlying rhythm and morphology. When depressed this button causes pacing stimuli to be delivered at ¼ the indicated ppm setting.

Pace Fault

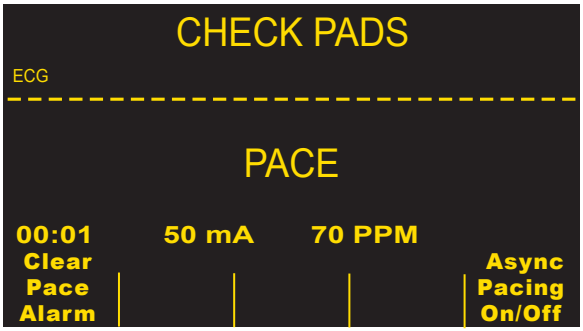
If the unit is attempting to deliver pacing therapy and one of the following conditions are true:

- the Multi-Function cable is not connected to the device,
- the cable is defective,
- MFE Pads are not connected to the Multi-Function cable,

or

- the MFE Pads are not making good skin contact.

The messages "CHECK PADS" and "POOR PAD CONTACT" are alternately displayed on the screen and an audible alarm sounds. The alarm will continue to sound until the left-most softkey (**Clear Pace Alarm**) is pressed.



Special Pacing Applications

Noninvasive Temporary Pacing may be performed in the Cardiac Cath Lab, either for emergency pacing or in standby mode. Radiolucent Stat-Pad**z** are available to facilitate pacing in X-ray and fluoroscopic applications.

Noninvasive Temporary Pacing may also be performed in the Operating Room using Sterile Stat-Pad**z**.

CAUTION

- Under certain conditions it may not be possible to properly monitor or pace while electrosurgical apparatus is operating.

Observe the device carefully for evidence of proper operation.

Standby Pacing

For certain patients at risk of developing symptomatic bradycardia, it may be advisable to use the unit in standby mode. When used in standby mode, the unit automatically provides a pacing stimulus whenever the patient's heart rate drops below a predetermined level. Patient's ECG must be monitored using ECG leads and patient cables for this application. To use the device in standby mode:

1. Establish effective pacing (see instructions on previous pages). Note the mA output at capture and run an ECG strip to document ECG morphology during capture.
2. Set the mA output 10% higher than the minimum mA output necessary to effect consistent ventricular capture.
3. Turn the pacing rate (ppm) below the patient's heart rate. This suppresses pacing unless the patient's own rate drops below the set pacing rate. The pacing rate should be set at a level sufficient for adequate cardiac output.
4. Check the threshold periodically.

Asynchronous Pacing

If ECG electrodes are not available or there is some circumstance that prevents or interferes with the surface

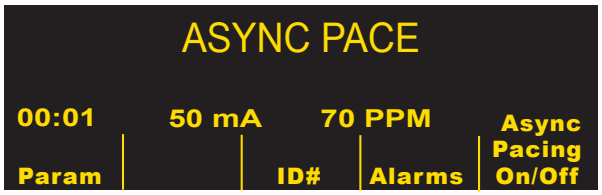
ECG, it may be necessary to operate the pacemaker asynchronously.

Asynchronous pacing should only be performed in emergency situations when there are no other alternatives.

To pace asynchronously:

Press the "Async Pacing On/Off" Softkey.

The display will show "ASYNC PACE" to indicate that asynchronous pacing has been activated. The annotation "ASYNC PACE" will be printed on the stripchart when activated by the RECORDER button. This annotation is also printed on the corresponding summary report. To return to demand pacing, press the ASYNC ON/OFF softkey again and the display will return to "PACE".



Pace stimuli will also be delivered asynchronously whenever there is an ECG LEAD OFF condition. You should be aware that there will be no ECG activity on the display when pacing by this method, and other means of determining capture such as checking the patient's pulse will be necessary. When asynchronously pacing with an ECG LEAD OFF condition, the rate and mA should be set at the known capture level or high enough (100mA) to presume capture.

Pediatric Pacing

Noninvasive pacing of pediatric patients is done in an identical manner to adult pacing. Smaller size pediatric MFE Pads are available for patients weighing less than 33 lbs/15 kg. Continuous pacing of neonates can cause skin burns. If it is necessary to pace for more than 30 minutes, periodic inspection of the underlying skin is strongly advised. Carefully follow all instructions provided on electrode package.

Troubleshooting

If your M Series unit does not function as expected, see the Pacer Troubleshooting section starting on page 11-4.

SECTION 8
ECG MONITORING

ECG leads are a defibrillation protected Type CF patient connection.

Introduction

The **M Series** products can be used for either short-term or long-term ECG monitoring.

M Series products have built-in protection circuitry to prevent damage to their ECG monitoring circuits during defibrillation attempts. Monitoring electrodes may become polarized during defibrillator discharge, causing the ECG waveform to briefly go off screen. High quality silver/ silver chloride (Ag/AgCl) electrodes minimize this effect, and circuitry in the instrument will return the trace to the monitor display within a few seconds.

ECG monitoring may be accomplished through an ECG patient cable, Multi-Function Pads or through standard defibrillation paddles. Use of an ECG patient cable and electrodes is required, however, to monitor during pacing.

Preparations

Proper application and placement of electrodes is essential for high quality ECG monitoring. Good contact between the electrode and skin minimizes motion artifact and signal interference.

Electrode Placement

Depending upon local usage, the ECG leads are marked either LA,RA, LL, RL, and V **or** L, R, F, N and C. Markings and color codes for the different lead sets are shown in the chart.

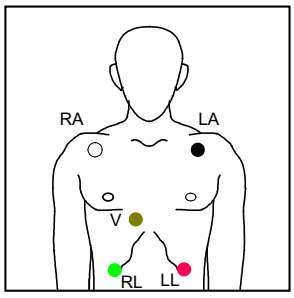
CAUTION

- To avoid electrosurgery burns at monitoring sites, ensure proper connection of the electrosurgery return circuit so that the return paths cannot be made through monitoring electrodes or probes.

During electrosurgery, observe the following guidelines to minimize ESU interference and provide maximum user and patient safety:

- Keep all patient monitoring cables away from earth ground, ESU knives and ESU return wires.
- Use electrosurgical grounding pads with the largest practical contact area, and
- Always assure proper application of the electrosurgical return electrode to the patient.

IEC Color Coding	AHA Color Coding	Placement of Electrodes
R/Red Electrode	RA/White Electrode	Place near right mid-clavicular line, directly below clavicle.
L/Yellow Electrode	LA/Black Electrode	Place near left mid-clavicular line, directly below clavicle.
F/Green Electrode	LL/Red Electrode	Place between 6th and 7th intercostal space on left mid-clavicular line.
N/Black Electrode	RL/Green Electrode	Place between 6th and 7th intercostal space on right mid-clavicular line.
C/White Electrode	V/Brown Electrode	Single movable chest electrode.



Attach Monitoring Electrodes

Peel the protective backing from the ECG electrode. Be careful to keep adhesive surface free of electrolyte gel.

Apply the ECG electrodes firmly to the patient's skin, pressing around the entire perimeter of the electrodes.

Attach snap-on leads and check for good contact between the electrode and the lead termination.

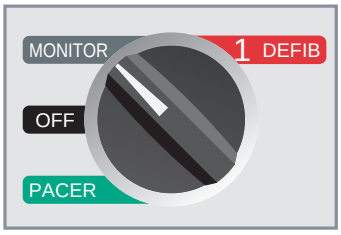
Plug the patient cable connector into the ECG input connector (located on the rear panel of the instrument).

Troubleshooting

If your M Series unit does not function as expected, see the Monitor Troubleshooting section starting on page 11-1.

Set the Controls

Set **SELECTOR SWITCH** to the **MONITOR** position.



Press the **LEAD** button until the desired lead configuration is selected (selected lead is indicated at upper right of display).

If the "ECG LEAD OFF" message appears on the display, inspect the ECG electrodes, lead wires, and associated connections. If a "CHECK PADS" or "POOR PAD CONTACT" message is displayed inspect the MFE Pads, cable, and associated connections.

If heart rate alarms are enabled with paddles selected, the unit displays the message "SELECT LIMB LEADS". If you see this message, select limb or precordial leads.

Press the **SIZE** button until the desired waveform size is displayed.

Adjust QRS beeper volume to suitable level using the beeper volume button.

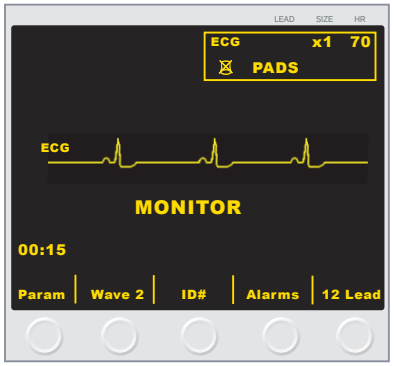
WARNING

- Implanted pacemakers may cause the heart rate meter to count the pacemaker rate during incidents of cardiac arrest or other arrhythmias. Pacemaker patients should be carefully observed. Check the patient's pulse; do not rely solely on heart rate meters. Dedicated pacemaker detection circuitry may not detect all implanted pacemaker spikes; patient history and physical exam are important in determining the presence of an implanted pacemaker.

Spikes from Implantable Pacemakers

The device is capable of detecting and indicating on the display pacemaker signals from a patient with an implantable pacemaker.

The device displays, a thin, solid line on the ECG trace whenever it detects a pacemaker signal. The waveform "spike" produced by the pacemaker will be displayed if the pacer is atrial, ventricular, or both.



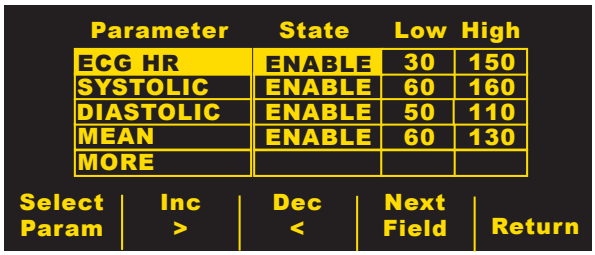
Alarms

Setting Alarm Limits

Unless configured otherwise, heart rate alarms are preset at 30 bpm (bradycardia) and 150 bpm (tachycardia). Refer to the Alarms Section of the Physiological Monitoring Parameter Insert(s) for further details specific to those parameters. (See the M Series Configuration Guide for details on setting power-up alarm limits.)

In order to set alarms the following sequence is used:

1. Press the **Alarms** softkey located below the display to view the Alarm Set screen and softkeys.
2. Press the **SELECT PARAM** softkey. This will scroll the highlighted area among the different possible vital signs. Select the state field for the parameter you wish to alter. The State field will be highlighted along with the selected vital sign field.



3. Press the **Inc** or **Dec** softkeys to select “ENABLE”, “DISABLE”, or “AUTO” in the State field. Pressing the **Next Field** softkey when either “ENABLE or “DISABLE” has been chosen will set the selected State and move the highlight to the next field (Low limit field).

   When “AUTO” has been selected and the **Next Field** softkey is pressed, the unit will set the lower and upper limits to 80% and 120% of the patient’s currently measured heart rate if valid measurements are present for the vital sign (Refer to appropriate Physiological Monitoring Parameter Insert(s) for differing percentages). The highlight then shifts to the next Parameter field.

Note: To alter the Low and High limits for any parameter when these limits have previously been set using the “AUTO” State, press the Inc or Dec softkeys to sequence through the “ENABLE” and “DISABLE” settings until “AUTO” is selected again and then press the Next Field softkey. The Low and High limits will automatically reset based upon the currently measured value of the selected physiological parameter.

4. If “AUTO” was not selected, press the **Inc** or **Dec** softkeys to set the Low alarm limit value. Press the **Next Field** softkey to confirm the selected value and move the highlight to the next field (High limit field). Repeat the step above for the High limit field.
5. Press the **Return** softkey to set all values and return to normal operating mode.

Alarm Function

The **M Series** device has three levels of alarms.

1. **High Priority:** If enabled, these alarms reflect physiological parameters that are out of bounds. They will cause a continuous audio tone, highlight the alarming parameter and flash the associated alarm bell.
2. **Medium Priority:** These alerts reflect equipment related user correctable faults such as LEAD OFF and CHECK SPO2 SENSOR. They will cause a two beep audio tone and display a message for a timed period.
3. **Low Priority:** These are informational messages to the user only and have the same audio indication as the Medium priority alarms.

Alarm Limits

The Low Heart Rate Alarm Limit range is 20 bpm to 100 bpm with a default setting of 30 bpm.

When a patient’s heart rate is being monitored, using ECG, the High Heart Rate Alarm Limit range is 60 to 280 bpm with a default setting of 150 bpm. When heart rate is being monitored using pulse oximetry, however, the maximum High Heart Rate Alarm Limit is lowered to 235 bpm automatically if it was previously set higher for ECG monitoring. The original High Alarm Limit setting will be restored when ECG monitoring resumes.

Suspending Alarms

When a high priority alarm occurs, a continuous audible tone will sound, the value of the alarming parameter will be highlighted and the bell associated with that parameter will flash.

Press the ALARM SUSPEND button to silence the alarm. An “X” will be placed through the flashing bell ( ) to indicate that alarms associated with the affected parameter have been audibly disabled. The value of the alarming parameter remains highlighted. Pressing the ALARM SUSPEND button again or correcting the alarm violation will reactivate the alarm processing.

If a second alarm occurs while the first alarm is suspended, press the **ALARM SUSPEND** button to suspend the second alarm tone.

Activating / Deactivating Alarms

Pressing and holding the Alarm Suspend button for approximately 3 seconds will deactivate alarm functions.

All bells will have an “X” through them ( ) to indicate that alarms are deactivated.

If all alarms are deactivated and the **Alarm Suspend** button is briefly pressed, all of the enabled alarm functions will be activated.

In Defib, Monitor or **ON** mode, ECG/heart rate alarm capabilities are enhanced with the defibrillation advisory feature called Smart Alarms™. When alarms are operating, this feature triggers an audible alarm

whenever ventricular fibrillation or wide complex ventricular tachycardias are detected. For advisory-triggered alarms, an additional "CHECK PATIENT" message will appear on the display and the chart recorder print out.

If alarms are operating in Pace mode (Pacing version only), the unit displays "VF ALARMS OFF", indicating that the Smart Alarms™ feature has been disabled.

If heart rate alarms are operating with paddles selected, the unit will display the message "SELECT LIMB LEADS". If you see this message, select limb or precordial leads. Better signal quality will be obtained using limb or precordial leads rather than paddles. To combine monitoring and defibrillation with heart rate alarms enabled, use MFE Pads.

Recorder Operation

The strip recorder will document the ECG trace with a 6 second delay at all times. To start the strip recorder, press the **RECORDER** button. The strip recorder will run continuously until the button is pressed again.

Each time the strip recorder is started, the time, date, ECG lead, size, and heart rate are printed on the top part of the paper. If the unit is pacing, the output current will also be printed. Similarly, if the defibrillator has been discharged, the delivered energy will be printed.

Note: The paper supply should be checked at the beginning of each shift and the end of each use to ensure adequate recording capability. A colored stripe on the paper means that the paper supply is low.

A "CHECK RECORDER" message appears on the display when the strip recorder is activated without paper. The strip recorder automatically shuts off when there is no paper.

Press the **RECORDER** button to start the strip recorder again after loading new paper.

If your M Series unit does not function as expected, see the Recorder Troubleshooting section on page 11-3.

Diagnostic Bandwidth

When using an ECG cable for monitoring, the unit can be switched to diagnostic bandwidth (0.05-150 Hz) by pressing and holding the **RECORDER** button depressed. Diagnostic bandwidth will be maintained as long as the **RECORDER** button is held down. The unit will revert to standard monitoring bandwidth when the **RECORDER** button is released.

Five (5) Lead Monitoring

Disconnect the 3-Lead ECG patient cable, if attached. Connect the five (5) lead ECG patient cable to the **M Series** product. Refer to the beginning of this section for appropriate Preparations (i.e., placement of electrodes, attaching electrodes, setting the controls, etc.) to be considered before performing five (5) lead monitoring.

If any ECG lead becomes disconnected during monitoring an "ECG LEADS OFF" message will appear on the display.

The "Smart Alarms" feature is always disabled during monitoring when augmented leads (AVR, AVF, AVL) or V-leads are selected. The messages "VF ALARMS OFF" and "SELECT LIMB LEADS" will be alternately displayed when alarms are activated (bell shaped character will appear on the upper portion of the display) and augmented leads or V-Leads are selected. These messages are only displayed the first time the augmented or V leads are selected. They are not redisplayed as the user cycles through the Lead selection.

Simultaneous 3 Lead Printing (If Configured)

To simultaneously print 3-leads of the patient ECG when leads are selected, a five (5) lead ECG cable must be in use and the "Print 3 Leads When Leads are Sel" option must be selected as "YES" in System Configuration (Refer to the M Series Configuration Guide).

The lead selection shown on the display will always be the top ECG printed on the recorder strip. Signals simultaneously recorded by the other leads of each triplet (limb leads, augmented leads, etc.) will be printed below this trace. For example, if AVR is selected, the recorder will simultaneously print AVR (top) followed by AVL (middle) and AVF (bottom).

Changing from Five (5) Lead to Three (3) Lead ECG Monitoring

To change from Five (5) Lead ECG monitoring to Three (3) Lead ECG monitoring, perform the following:

- Turn the unit OFF for at least 10 seconds.
- Disconnect the five (5) lead ECG patient cable from the back of the unit.
- Connect the Three (3) Lead ECG patient cable to the back of the unit.
- Turn the unit ON.

Note: The message, "ECG LEADS OFF will appear on the display if the unit was not turned OFF for at least 10 seconds after the Five (5) Lead ECG cable has been removed even if leads are properly attached to the patient.

Vital Signs Trending

Some M Series models include a vital signs trending feature that samples the instantaneous values of monitored physiological parameters and stores the sampled data in a log that includes the time these values were recorded. These vital signs include the patient's heart rate, SpO_2, end tidal CO_2, respiration rate and noninvasive systolic, diastolic and mean blood pressure values.

Stored trend data may then be viewed in tabular form on the M Series display or printed by the unit's stripchart recorder.

If the M Series is configured with trending enabled, the values of monitored vital signs are sampled once each minute and stored in the unit's trend memory. Storage is provided for 24 hours of one minute trend records. When this storage is filled, the newest trend record replaces the oldest trend record. Additional trend records will be stored whenever a parameter alarms or an NIBP measurement is taken. Note that these additional records will decrease the overall number of one minute trend records that can be stored in the unit's memory.

Viewing Vital Signs Trending Data on the Display

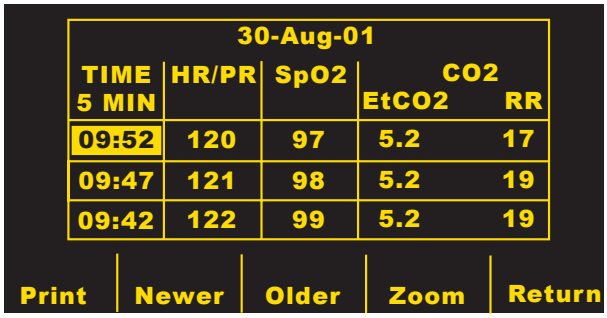
The display for vital signs trend data always shows the time of the recorded data, the heart rate/pulse rate and the SpO_2. The date of the recording appears at the top of the trend display. $EtCO_2$ and NIBP are optionally displayed based on the configuration of the unit.

To select either $EtCO_2$ or NIBP data for viewing:

1. Press the **SUMMARY** button.
2. Press the **Trend** softkey on the Summary menu.
3. Use the **Select** softkey to highlight either $EtCO_2$ or NIBP.
4. Press the **Enter** softkey to select the desired option.

To view only SpO_2 data when multiple parameters are installed on the unit, use the **Select** softkey to highlight SpO_2 from the **Trend** submenu, then press the **Enter** softkey.

If only one parameter is installed on the unit, the trend screen automatically displays when the **Trend** softkey is pressed.



Not all trend data can be displayed on the monitor at the same time. However, the screen can be changed to display additional recorded data. Using the **Zoom** softkey, the user can view trend records taken at 1 minute, 5 minute, 10 minute, 15 minute, 30 minute, and 60 minute intervals. Data is presented with the newest at the top to the oldest at the bottom of the display.

If an alarm occurs while the unit is monitoring vital signs, such as an NIBP alarm, the unit records the data at the moment of the alarm independent of the standard one minute interval recording.

An alarm condition is indicated on the trend display by placing brackets around the alarmed parameter(s). Invalid data is indicated on the display by substituting a dashed line for the actual data. Invalid data may occur, for example, when the measuring probe or device is not properly connected to the patient.

The most recently recorded values are indicated by highlighting the time stamp associated with the trend data. If no time record is highlighted, older data is being displayed. To view the newest values of recorded data, press the **Newer** softkey until the highlighted time displays.

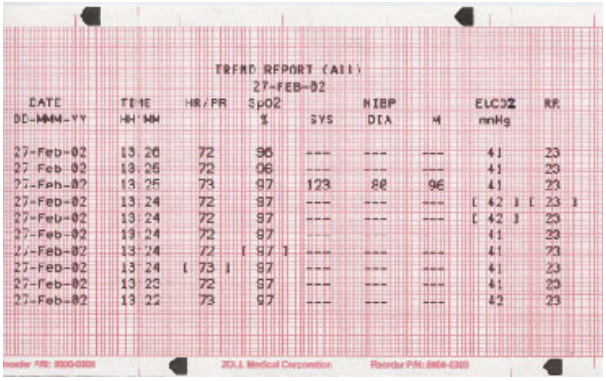
When viewing the newest data, the display automatically updates as each new trend record is recorded. To view older values of recorded data, press the **Older** softkey until the desired data displays. After three minutes has elapsed since the last softkey activation while viewing older data, the physiological monitoring menu returns to view.

Printing a Vital Signs Trend Report

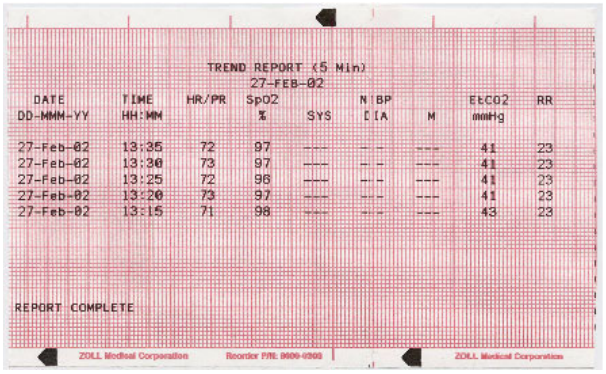
The stripchart prints the trend report using the same zoom level that the display uses. If the Zoom setting is set to 1 minute, pressing the Print softkey on the Trend display causes all trend data to print out.

Data is printed on the stripchart in order of newest data to oldest data. Alarm conditions are indicated on the stripchart by placing brackets around each alarmed parameter. As on the display, invalid data is indicated by substituting a dashed line for the actual data.

NIBP readings are considered valid for only one trend record (i.e., the minute during which the NIBP measurement was completed). All other trend records indicate invalid NIBP readings.

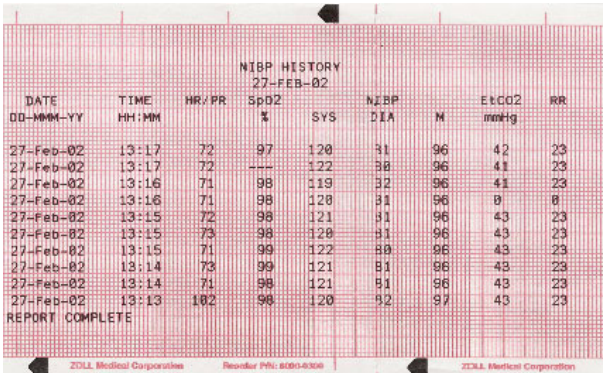


If the Zoom setting is set to 5 minutes (for example), pressing the Print softkey on the Trend display causes a "zoomed" report to print out.


TREND REPORT (5 Min)
27-FEB-02
DATE TIME HR/PR SpO2 NIBP EtCO2 RR
DD-MMM-YY HH:MM % SYS DIA M mmHg
27-Feb-02 13:35 72 97 --- --- --- 41 23
27-Feb-02 13:30 73 97 --- --- --- 41 23
27-Feb-02 13:25 72 96 --- --- --- 41 23
27-Feb-02 13:20 73 97 --- --- --- 41 23
27-Feb-02 13:15 71 98 --- --- --- 43 23
REPORT COMPLETE

NIBP Trend Operation

When displaying NIBP trends, only those records containing actual NIBP readings are displayed. NIBP trend reports contain all NIBP records regardless of the Zoom level.



Clearing Vital Signs Trend Records

Up to 24 hours of trend data can be stored before it is overwritten. If the unit is powered down while recording trend data, the corresponding gap in time will be indicated on the display by a series of asterisks in the time field. On the stripchart, this gap is indicated by advancing the stripchart paper and starting a new page of trend data. If the unit is turned off for more than a user specified length of time, all vital signs trend data is automatically erased.

To clear trend data, press and hold the SUMMARY button until the display shows the Erase Summary, Erase Trend and Erase All softkeys. Press the Erase Trend softkey. The ERASING REPORT message displays and the trend data is cleared.

SECTION 9
GENERAL MAINTENANCE

Periodic Testing

Resuscitation equipment must be maintained to be ready for immediate use. The following operational checks should be performed at the beginning of every shift to ensure proper equipment operation and patient safety.

Refer to the appropriate Operator's Shift Checklist at the end of this section. Copy and distribute the appropriate sheet to all individuals responsible for the device's use and readiness.

Note: Self-test defibrillation and pacing data is automatically recorded on the PCMCIA data card, if present. The unit can be configured to erase all self-test data from the data card on power-off. See the M Series Configuration Guide for more information.

Inspection

Assure that the unit is clean (with no fluid spills) and nothing is stored on the unit.

Assure that two sets of MFE Pads are available in **sealed packages.** Check expiration dates on all MFE Pads packages.

Check that the paddle surfaces are clean and free of electrolyte gel and other contaminants.

Inspect all cables, cords, and connectors for good condition, lack of cuts or fraying, and absence of bent pins.

Verify the presence and proper condition of all disposable supplies (electrode gel, monitoring electrodes, recorder paper, alcohol swabs, razors, antiperspirant).

Check that an empty memory card is installed in the unit (if applicable).

Check that a fully charged battery is installed in the unit.

Check that a fully charged spare battery is with the unit.

Cleaning

The M Series products and their accessories are chemically resistant to most common cleaning solutions and non-caustic detergents. The following list includes approved cleaning solutions;

- 90% Isopropyl alcohol (except adapters and patient cable)
- Soap and water
- Chlorine bleach (30ml/l water)

ZOLL recommends cleaning the device, paddles, and cables with a soft damp cloth, and cleaning agents mentioned. The recorder parts should be cleaned with a damp, soft cloth only.

Do not immerse any part of the device (including paddles) in water. Do not use ketones (MEK, acetone, etc.). Avoid using abrasives (e.g., paper towels) on the display window. Do not sterilize the device.

Special care should be taken to clean the defibrillation paddles after each use. Build up of gel will interfere with paddle ECG (first look) monitoring and may produce a shock hazard to the operator. Keep paddle handles clean.

Cleaning the Recorder Printhead

To clean the Recorder printhead perform the following steps:

1. Press down and pull the Paper Compartment drawer where the "**RELEASE**" label is located.
2. Remove the paper (if necessary).
3. Pull drawer out all the way.
4. Tip unit backwards so that the bottom of the drawer is easily visible.
5. Locate plastic tab in the back of the drawer.
6. Press tab (disengaging plastic ridge) and pull drawer until removed.
7. Locate the row of soft, thin bristles.
8. Locate a thin black line (Printhead) adjacent and parallel to the bristles.
9. Gently wipe the thin black line with an alcohol (Isopropyl) moistened Q-tip. Dry any residual alcohol with a new Q-tip.
10. Place drawer and paper back into the unit.

Semi-Automatic Defibrillator Testing

1. Power-Up Sequence Check

Connect the patient end of the multifunction cable to the defibrillator test connector.

Starting with the selector switch OFF, turn the selector switch to the **ON** position and observe the following:

- A 4-beep tone indicates the power-up self test has been successfully completed.
- The CHECK PADS message is displayed and announced.

2. Defibrillator Test

- Press the **ANALYZE** button. Verify the unit charges to 30J (30J Ready message).
- Once unit has charged, verify the **SHOCK** button illuminates.
- Press and hold the **SHOCK** button.
- TEST OK should be briefly displayed on the screen and printed on the strip chart recorder (if present). These messages indicate that the unit delivered energy within specifications.
- If "TEST FAILED" appears, contact appropriate technical personnel or ZOLL Technical Service Department immediately.
- Attach the Multi-Function cable to the ZOLL ECG Simulator. Set the Simulator to VF.
- Verify that within 30 seconds the "CHECK PATIENT" message is displayed and announced.
- Press the **ANALYZE** button. Verify the unit charges to 200J (non-Biphasic), or 120J (Biphasic) or other preconfigured level.
- Once unit has charged, verify the **SHOCK** button illuminates and the "PRESS SHOCK" message is displayed and announced.
- Press and hold the **SHOCK** button. Verify unit discharges.

3. Recorder Check (if applicable)

- Check for adequate supply of paper.
- Press the **RECORDER** button. The strip recorder will run until the **RECORDER** button is pressed again.
- Inspect the recorder waveform for uniformity and darkness.
- Inspect for uniformity of annotation characters and completeness of words.

  If a "LOW BATTERY" message appears during testing at the beginning of a shift, the battery currently in use is close to depletion and should be replaced and charged. The device does not test the battery for adequate charge to support extended use of the unit, capacity can only be determined by testing the battery in an appropriate ZOLL Battery Charger.

Manual Defibrillator Testing

1. Power-Up Sequence Check

Starting with the selector switch OFF, turn the selector switch to the **MONITOR** position and observe the following:

- A 4-beep tone indicates the power-up self test has been successfully completed.
- The ECG size should be x1 and the word "MONITOR" should appear in the center of the display screen.
- "PADDLES" or "PADS" should be displayed in the top right center of the monitor.
- The message "ECG LEAD OFF" will be displayed and the ECG display will be a dashed line instead of a solid line if no ECG cable is connected to the simulator.

2. Delivered Energy and Shock Buttons

WARNING

- When performing this check using paddles, use your thumbs to operate the **SHOCK** buttons in order to avoid an inadvertent shock. No portion of the hand should be near the paddle plates.

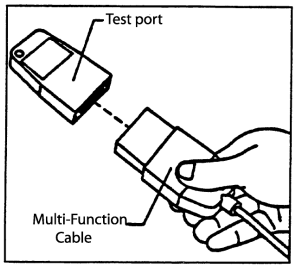
Perform this check at the start of each shift using either the paddle or Multi-Function cable setup (described below) as applicable to your situation.

Paddle Setup

- Verify adult paddles are installed and are pushed all the way into their holders on the side of the M Series unit.
- Turn the selector switch to **DEFIB**.
- Set the defibrillator energy level to 30 joules.
- Press the **CHARGE** button on the apex handle.
- When charge ready tone sounds, use the defibrillator energy select buttons on either the sternum paddle or defibrillator front panel to change the selected energy to 20 joules.
- The defibrillator will disarm itself.
- Use the defibrillator energy select buttons on either the sternum paddle or defibrillator front panel to change the selected energy back to 30 joules.

Multi-Function Cable Setup

- The Multi-Function Cable should be plugged into the unit. Make sure the Multi-Function Cable is not plugged into its test connector.
- Switch unit to **DEFIB** and set energy to 30 joules.
- The messages “CHECK PADS” and “POOR PAD CONTACT” will be alternately displayed.
- Plug the Multi-Function Cable into its test connector.
- The message “DEFIB PAD SHORT” will be displayed.



3. Energy Delivery Test (Paddles/MFE Pads)

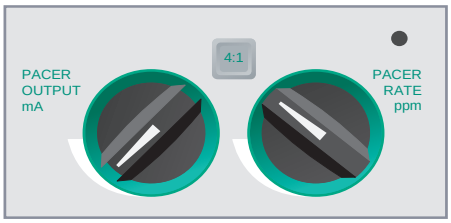
- Press the **CHARGE** button on the front panel or on the apex paddle handle.
- Wait for the charge ready tone to sound and verify that the energy ready value displayed on the monitor registers 30 joules (“DEFIB 30J READY”).
- If paddles are installed, using your thumbs, simultaneously press and firmly hold the **SHOCK** buttons (one on each paddle) until discharge occurs.
- If MFE cable and test connector are installed, press and hold the **SHOCK** button on the front panel of the defibrillator until discharge occurs.
- The strip chart recorder will print a short strip indicating “TEST OK” and energy delivered if the unit delivered energy within specifications.
- If “TEST FAILED” appears, contact appropriate technical personnel or ZOLL Technical Service Department immediately.

Note: During the Energy Delivery Test, unit will only discharge when energy level is set to 30 joules.

4. Pacer Operation (Pacer Version Only)

- Turn the **SELECTOR SWITCH** to **PACER**.
- Turn **PACER RATE** control to 150 ppm.
- Press the **RECORDER** button to generate a strip.

- Verify that the pacing stimulus markers (⊓⊔) occur approximately every 10 small divisions (2 large divisions, 1 cm).
- Press the **4:1** button and verify that the frequency of the markers decrease (8 large divisions, 4 cm between each marker).



- Turn the **PACER OUTPUT** control to 0 mA. There should be no “CHECK PADS” or “POOR PAD CONTACT” messages.
- Disconnect MFE Pads or paddles from the Multi-Function cable.
- Slowly turn the knob up to 16 mA. The “CHECK PADS” and “POOR PAD CONTACT” messages are alternately displayed on the screen. Pace alarm sounds and flashes.
- Connect Multi-Function cable to test connector.
- Press the **Clear Pace Alarm** softkey. The “CHECK PADS” and “POOR PAD CONTACT” messages disappear and the Pace alarm stops.

5. Recorder Check

- Check for adequate supply of paper.
- Press the **RECORDER** button. The strip recorder will run until the **RECORDER** button is pressed again.
- Press and hold the **SIZE** button for at least 2 seconds to generate a calibration pulse. The calibration pulse will remain on the display for as long as the **SIZE** button remains depressed. In addition, the amplitude of the calibration pulse is 1 mv independent of the **SIZE** setting.
- Inspect the recorder waveform for uniformity and darkness.
- Inspect for uniformity of annotation characters and completeness of words.
- Check strip recorder speed by verifying that the calibration pulse is 2.5 ± ½ mm wide and 10 ± 1 mm high.

Changing Paper

Press down and pull the paper tray drawer where the "RELEASE" label is located. The drawer slides open.

Check for adequate paper supply. If paper supply is low, remove paper in the tray. Place a new pad of thermal paper in the drawer with the paper coming off the top of the pad and the grid facing up.

Pull enough paper off the pad so that the paper extends out of the strip recorder when the paper compartment drawer is closed.

Close paper compartment drawer by pushing the drawer in and pressing down lightly where the "RELEASE" label is located until the drawer is flush with the front of the device.

Setting Time and Date

Check the time and date on the recorder annotation. If it is not correct, set as follows:

Turn the **SELECTOR SWITCH** to **OFF**. The device must remain off for at least 10 seconds before entering the "Set Time" screen for setting the time manually as described in the subsection "Manual Method" below, or in Utilities Mode for setting the time automatically. See the subsection "Automated Method" below for instructions on setting the time automatically.

Manual Method

1. Press and hold the right-most softkey on the unit while turning the **SELECTOR SWITCH** to the **MONITOR or ON** position. When the "Set Time" screen appears on the monitor, release the softkey.

2. The month field will be highlighted. Press the **Inc Value** or **Dec Value** softkeys to select the appropriate month. Pressing the **Next Field** softkey will set the selected month and move the highlight to the next field (day).
3. Repeat above steps to set the correct day, year, hours and minutes field.

Note: The last field does not automatically scroll (wrap) to the beginning. You must press the **Prev Field** softkey to enter the values for the last field.

If you need to make corrections, press **the Prev Field** softkey to move the highlight to the field previously entered.

4. Press the **Enter and Return** softkey to set all values and return to normal monitoring mode.

Automated Method

Note: This method requires a modem connection. In addition, the correct time zone must be set in System Configuration mode for the updated date and time to be correct.

1. Press and hold the left-most softkey on the unit while turning the **SELECTOR SWITCH** to the **MONITOR or ON** position. When the "System Utilities" screen appears on the monitor, release the softkey.
2. Press the **Clock Sync** softkey. A setting screen appears, allowing the user to choose a NIST (National Institute for Science and Technology) location and a prefix for the phone number of the selected NIST location, as required. For example, if the NIST location is outside of the local calling area, users within the continental United States would enter a "1" as the dial prefix. Other users would enter a dial prefix as required for placing calls in the continental United States.
3. Press the **Dial** softkey. The word "Initializing" appears briefly, followed by the "Clock Synchronization" screen, displaying the user configurable NIST phone number with the appropriate prefix. The word "Dialing" appears underneath, along with a seconds counter, as the unit connects to the NIST site.

After receiving the atomic clock information from the NIST site, the unit then displays updated date and time information, unless one of the following errors occurs:

Error Message	Description/Corrective Action
MODEM REQUIRED	The unit determined that there is no modem card installed. Install a supported modem card and retry.
MODEM INIT ERROR	The modem could not be initialized. Replace the modem card and retry.
NO DIAL TONE	The unit could not detect a dial tone. Check the connection between the modem and the phone jack, or try a different phone line.
BUSY	The unit detected a busy signal from the selected NIST location. Retry.
NO ANSWER	The unit received no answer from the selected NIST location. Retry or select another NIST location.
NO CARRIER	The unit determined that the line is broken. Correct the line break and retry.

Error Message	Description/Corrective Action
HANG UP	The unit received a hang up indication from the selected NIST location. Retry.
MODEM DIAL ERROR	The modem could not dial the phone number. Ensure that the modem card is properly connected. Ensure that the user-selected dial prefix (set in the System Configuration or System Utilities mode) is correct. Retry.
NIST DATA ERROR	The unit detected an error in the data from NIST. Retry.

Verify that the time and date are set correctly by generating a strip chart recording. Press the **RECORDER** button and check that the strip chart is correctly annotated with the current time and date, selected ECG size, source, and heart rate.

Verify that the real-time clock is operating correctly by waiting for several minutes then running the strip recorder again.

Note: Time and date may require resetting if the devices' internal battery is depleted or the time zone has changed.

Operator's Shift Checklist for M Series Products (Manual)

Recommended checks and procedures to be performed at the start of each shift. For more detailed information, see the M Series Operator's Guide.

Date _____

Location _____

Unit Serial Number _____

1. Condition	1st Shift	2nd Shift	3rd Shift	Remarks
Unit clean, no spills, clear of objects on top, case intact				
2. Multi-function Pads				
1 set pre-connected / 1 spare				
3. Paddles				
Paddles clean, not pitted				
Release from housing easily				
4. Inspect cables for cracks, broken wires, connector				
A ECG electrode cable, connector				
B Defibrillator paddle cables				
C Multi-function cable, connector				
5. Batteries				
A Fully charged battery in unit				
B Fully charged spare battery available				
6. Disposable supplies				
A Electrode gel or gel patches				
B MFE Pads in **sealed** pouches — 2 sets				
C ECG electrodes				
D Recorder paper				
E Alcohol wipes				
F Razors				
7. Operational checks				
A Power On Sequence				
Turn unit to MONITOR, 4-beep tone heard				
"MONITOR" message on display				
ECG size X 1				
"PADDLES" or 'PADS" as lead selected				
B Pacer Operation (Pacer Version ONLY)				
Multi-function cable not connected to Test Connector				
Turn to PACER, set pacer rate to 150 ppm, press RECORDER button				
Pacer pulses occur ever 2 large divisions (10 small divisions)				
Press 4:1 button, pulses occur every 8 large divisions				
Set PACER OUTPUT to 0 mA, no "CHECK PADS" message				
Set PACER OUTPUT to 16 mA, "CHECK PADS" message and alarm				
Reconnect Multi-function cable to test connector.				
Press Clear Pace Alarm softkey; "CHECK PADS" message disappears and Pace alarm stops.				
C Defibrillator				
Multi-function cable connected to test connector: Set defib energy level to 30 joules, press **SHOCK** button; "TEST OK" message on Recorder				
D Paddles				
Paddles in holder: Set defib energy level to 30 joules, press paddles firmly into the side wells, and simultaneously press and hold both defib discharge buttons; "TEST OK" message on Recorder.				
E Recorder				
Press RECORDER button; Recorder runs. Press again; Recorder stops.				
Inspect Recorder printing				

8. Please check the appropriate box after each use of this checklist.			
No action required			
Minor problem(s) corrected			
Disposable supplies replaced			
Major problem(s) identified — UNIT OUT OF SERVICE			

Signatures

1st _____

2nd _____

3rd _____

Operator's Shift Checklist for M Series Products (Semi-Automatic)

Recommended checks and procedures to be performed at the start of each shift. For more detailed information, see the M Series Operator's Guide.

Date _____

Location _____

Unit Serial Number _____

1. Condition	1st Shift	2nd Shift	3rd Shift	Remarks
Unit clean, no spills, clear of objects on top, case intact				
2. Multi-function Pads				
1 set pre-connected / 1 spare				
3. Paddles (if applicable)				
Paddles clean, not pitted				
Release from housing easily				
4. Inspect cables for cracks, broken wires, connector				
A ECG electrode cable, connector				
B Defibrillator paddle cables				
C Multi-function cable, connector				
5. Batteries				
A Fully charged battery in unit				
B Fully charged spare battery available				
6. Disposable supplies				
A Electrode gel or gel patches				
B MFE Pads in **sealed** pouches — 2 sets				
C ECG electrodes				
D Recorder paper				
E Alcohol wipes				
F Razors				
7. Operational checks **A Power On Sequence**				
Turn unit to ON, 4-beep tone heard				
B Defibrillator				
Multi-function cable connected to test connector: "CHECK PADS" displays.				
Press **ANALYZE** button, unit charges to 30 J				
Press and hold **SHOCK** button, "TEST OK" is displayed and printed				
Attach MFC to ECG Simulator, set to VF				
Verify "CHECK PATIENT" message is displayed				
Press ANALYZE. Verify unit charges to 200 J				
Press SHOCK, verify shock was delivered.				
C Paddles (if applicable) (Manual Mode ONLY)				
Paddles in holder: Set defib energy level to 30 joules, press paddles firmly into the side wells, and simultaneously press and hold both defib discharge buttons; "TEST OK" message on Recorder.				
D Pacer Operation (Manual Mode ONLY)				
Multi-function cable not connected to Test Connector				
Turn to PACER, set pacer rate to 150 ppm, press RECORDER button				
Pacer pulses occur ever 2 large divisions (10 small divisions)				
Press 4:1 button, pulses occur every 8 large divisions				
Set PACER OUTPUT to 0 mA, no "CHECK PADS" message				
Set PACER OUTPUT to 16 mA, "CHECK PADS" message and alarm				
Reconnect Multi-function cable to test connector.				
Press Clear Pace Alarm softkey; "CHECK PADS" message disappears and Pace alarm stops.				
E Recorder				
Press RECORDER button; Recorder runs. Press again; Recorder stops.				
Inspect Recorder printing				

8. Please check the appropriate box after each use of this checklist.			
No action required			
Minor problem(s) corrected			
Disposable supplies replaced			
Major problem(s) identified — UNIT OUT OF SERVICE			

Signatures

1st _____

2nd _____

3rd _____

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SECTION 10
BATTERY MANAGEMENT

Battery Care

WARNING

- Regular use of partially charged battery packs without fully recharging between uses will result in permanently reduced capacity and early battery pack failure.

Safe, reliable use of the system requires a well designed battery management program to ensure that adequate battery power is always available.

ZOLL has developed the ZOLL Battery Management Program booklet. It includes information for determining your particular battery requirements and program implementation steps to setup a comprehensive, effective and safe program.

For safe disposal of lead acid batteries and disposable electrodes, follow your national, state, and local regulations. In addition, to prevent risk of fire or explosion, never dispose of the battery in a fire.

Battery Life Expectancy

Lead acid battery packs require full recharging after use. Repeated short cycle recharging will result in reduced capacity and early battery pack failure.

Frequency of use, number of batteries used for operation, and the pattern of discharging and recharging batteries contribute to the loss of battery charge capacity. Because of this, ZOLL recommends that operators replace and discard used batteries on a preventive, scheduled basis. The most effective preventive replacement interval should be based on anticipated use patterns, battery pack testing results and experience with the device in actual operation.

ZOLL recommends battery replacement every eighteen months or sooner.

Low Battery Message

A “LOW BATTERY” message will be displayed on the monitor once every minute, and a 2-beep low battery tone will sound (optionally) once every minute or once every 5 minutes whenever the unit detects a LOW BATTERY condition. Replace the battery pack immediately to ensure continuous operation.

This message and beeping will persist until just before device shutdown when the unit beeps twice and the “REPLACE BATTERY” message appears for approximately 20 seconds.

The time from display of the “LOW BATTERY” message until the instrument shuts down will vary depending upon the battery age and condition.

WARNING

- Test batteries regularly. Batteries that do not pass ZOLL’s capacity test could unexpectedly shutdown without warning.

Replace the battery with a fully-charged battery immediately after the “LOW BATTERY” or “REPLACE BATTERY” message.

As individual battery capacity diminishes, the amount of operating time remaining after a “LOW BATTERY” message also diminishes. For newer or lesser-used batteries, the operating time remaining after this warning will be significantly longer than the operating time remaining with batteries having seen more use. In either case, this warning will ultimately lead to defibrillator shut-off, and consequently, the low battery should be replaced with a fully-charged battery as soon as possible.

Changing the Battery Pack

The **M Series** products are designed for quick removal and replacement of the battery pack.

To remove the battery pack, turn the unit off. Insert a finger into the recess at the left end of the battery pack, press against the battery pack to disengage the battery pack locking clip and lift the battery pack out.

To install a battery pack, align the tab of the battery pack case with the battery pack removal finger recess on the top of the unit. Set the battery pack into the battery pack well. The shape of the battery pack will allow the battery pack to seat itself. Turn the defibrillator back on to the selected mode of operation.

If the unit is set to PACE mode, pacing may resume immediately after battery replacement. If this is not desired, then turn the unit off for more than 10 seconds prior to replacing the battery. When operation of the unit is resumed subsequent to battery replacement, the unit's settings (for example, alarms, lead, pacing amplitude and rate) should be re-verified.

Charging and Testing Battery Packs

ZOLL batteries are designed to be charged in the device or other accessory chargers designed for use with ZOLL devices (XL battery packs also require M Series software version 30.0 or higher). ZOLL recommends that you always have a ZOLL auxiliary battery charger available in order to charge spare batteries and perform periodic battery testing.

The ZOLL Base PowerCharger^{4x4} was designed specifically for this purpose. *

With the M Series unit plugged in and turned off, the device will recharge the PD4410 battery within 4 hours, and the XL battery pack in 7.2 hours. With the M Series unit plugged in and in use, the device will recharge a fully depleted PD4410 battery pack in 24 hours, and the XL battery pack in 32 hours.

Battery charging can be performed within the device or by using an external battery charger.

When the **M Series** products are plugged into AC mains, the **CHARGER ON** indicators will operate in the following manner:

The orange-yellow **CHARGER ON** indicator will illuminate continuously whenever; the device is turned OFF and charging the battery or turned ON with a battery installed.

The green **CHARGER ON** indicator will illuminate continuously whenever; the unit is turned OFF and the installed battery has been fully charged to present capacity.

The green and orange-yellow **Charger On** indicators will illuminate alternately when; **no** battery is installed in the unit or a battery charging fault has been detected.

When the device is not connected to AC mains, the **CHARGER ON** indicators will remain extinguished.

Achieving Optimal Battery Pack Performance

The following general practices will ensure the longest life from your battery pack:

"Do's and Don'ts" in using battery packs:

- ***DO charge battery packs completely.***

  When a battery pack exchange is required, place a fully charged battery in the unit.

  If use of a partially-charged battery pack is required, it may result in a very short Monitor/Defibrillator run time.

  If a partially charged battery pack is used, a full charge is recommended before its next use. Repeated use after partial charging will quickly diminish the battery pack's capacity, thereby shortening its life.

  Frequent use of partially charged batteries requires reassessment as to whether enough battery packs are in service.

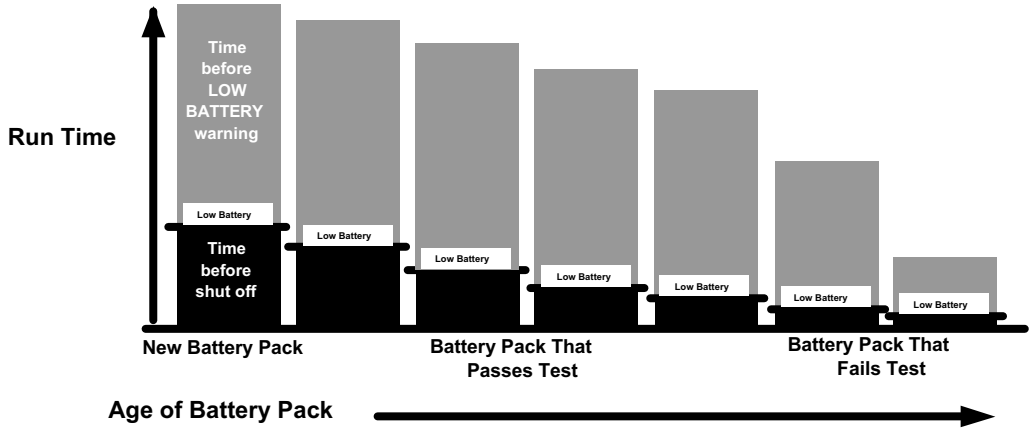
- ***DO change Battery Packs when "LOW BATTERY" warning occurs.***

  The "Low Battery" warning will ultimately lead to Monitor/ Defibrillator shut down. As batteries age, the run time between "Low Battery" warning and Monitor/ Defibrillator shut down will progressively diminish. Older batteries may provide very little run time between "Low Battery" warning and Monitor/Defibrillator shut down. Therefore, when the "Low Battery" warning occurs, a fully charged Battery Pack should be installed as soon as possible.

*** For XL Battery packs, the Base PowerCharger^{4x4} must be labeled "XL Battery Ready".**

Figure 1 illustrates the effect of lowered battery capacity on the Monitor/ Defibrillator operating time remaining after "LOW BATTERY" warning.

Figure 1



- ***DO <u>test</u> Battery Packs regularly.***

  Your organization must determine and implement an appropriate testing schedule. Adherence to this schedule is crucial to identifying Battery Packs that have reached end of life and should be removed from use. Battery Packs subjected to repeated short discharge and charge cycles may lose their capacity quickly. Battery Packs used this way should be tested more frequently.

- ***DO implement a means of indicating the charge status of Battery Packs.***

  It is important to visibly distinguish Battery Packs that are charged from those that are not. Establish a system for visually indicating whether a Battery Pack is charged and ready for use or is in need of charging. ZOLL can provide you with Battery Pack Status Labels for this purpose, or you can use labels or methods of your own.

- ***DO exchange your Battery Packs regularly.***

  Battery Packs should be exchanged once per shift or once per day depending on their use.

- ***DO carry a fully charged spare Battery Pack at all times.***

- **DON'T remove a partially charged Battery Pack from the battery charger**.

  If a partially charged Battery Pack is used, a full charge is recommended before its next use. Repeated use after partial charging will quickly diminish the battery's capacity, thereby shortening its life.

- **DON'T store Battery Packs in a discharged state.**

  Battery Pack capacity will diminish if left in a discharged state for extended periods.

- **DON'T assume that a shift check of the Monitor/Defibrillator verifies adequate Battery Pack run time.**

  Your Monitor/Defibrillator should be tested daily to verify the readiness of the device. This test, however, does not verify adequate charge state or capacity of the Battery Pack and may leave the Monitor/Defibrillator with inadequate run time.

  If the device shows a "LOW BATTERY" warning during testing, the Battery Pack should be replaced and recharged.

- **DON'T place Battery Packs charged with a Base PowerCharger ^{4x4}, a PowerCharger or a PD 4420C (constant current chargers) into the PD 4420 or Single Battery Charger (constant voltage charger) without providing a rest period of at least 12 hours.**

  This will result in damage to the Battery Packs.

- **DON'T charge Battery Packs at temperature extremes.**

  ZOLL recommends charging Battery Packs at or near normal room temperature (15°C to 35°C or 59°F to 95°F).

- **DON'T leave batteries in a depleted state.**

  Once a battery is removed from the device it should be immediately placed in a charge or test well. Idle batteries will lose some of their charge and may suffer damage to charge capacity if left in a discharged state.

SECTION 11
TROUBLESHOOTING GUIDES

The troubleshooting guides provided on the following pages are intended for use by non-technical medical personnel during device operation. This section answers many of the common problems or questions that may arise during operation.

If trouble persists after consulting this guide, contact the appropriate technical personnel or ZOLL Technical Service Department. A more detailed troubleshooting guide is found in the *M Series Service Manual*.

General

Monitor

Symptom	Recommended Action
1. Unit does not turn on or unexpectedly shuts off.	• Check that battery pack is properly installed. • Verify the unit is plugged into AC power. • Replace battery pack with a fully charged battery pack.
2. “X FAULT XX” message	• A fault has been detected. • Attempt to clear the **“X FAULT XX”** message by turning the **SELECTOR SWITCH** to **OFF** then back to the desired operating mode. **Note:** Some settings (e.g. alarm settings, lead selection, ECG size) may need to be restored.
3. “SET CLOCK” message	• Set time and date information. • Verify that the internal lithium battery has been replaced within the last 5 years. Contact ZOLL Technical Service Department for assistance
4. “ECG LEAD OFF” message	• Check that ECG cable is connected to patient and instrument. • Check that ECG electrodes are making good contact and not dried out. • If changing from five (5) lead ECG patient cable to three (3) lead ECG patient cable, turn unit OFF for at least 10 seconds. • Replace ECG cable

Symptom	Recommended Action
5. "POOR LEAD CONTACT" message	• Check that ECG cable is connected to patient and instrument. • Check that ECG electrodes are making good contact and not dried out. • If changing from five (5) lead ECG patient cable to three (3) lead ECG patient cable, turn unit OFF for at least 10 seconds. • Replace ECG cable.
6. Noisy ECG, Artifact, Wandering Baseline	• Consider 1 – 21Hz filter bandwidth (see M Series Configuration Guide) • Prepare the patient's skin prior to electrode attachment. • Check for proper adhesion of electrodes to patient. • Reduce or eliminate ECG artifact due to electrode or patient cable movement. Route cables so that they don't pull on electrodes or swing excessively. • Ensure patient is motionless. • Check for possible excessive radio frequency interference.
7. Poor ECG signal level, calibration pulse normal.	• Select another lead. • Apply new electrodes using different placement.
8. Inconsistent QRS beep or heart rate.	• Increase beeper volume. • Select another lead. • Alter ECG electrode placement.
9. Sync marker is absent or inconsistent with QRS waveform on display and recorder.	• Ensure device is in SYNC mode. • Change ECG lead selection. • Alter ECG electrode placement. • Paper too narrow. It should be 90 mm wide.

Recorder

Symptom	Recommended Action
10. "CHECK RECORDER" message.	• Recorder out of paper. • Remove paper, check paper type, check recorder for paper jam, reload paper. • Recorder door is open.
11. Recorder makes stuttering sound when activated.	• Check recorder for paper jam.
12. Light or poor quality printing.	• Ensure correct paper is in use. • Ensure paper is installed grid side against recorder print head. • Recorder print head requires cleaning (trained personnel only).
13. Summary Report will not print when **SUMMARY** button is depressed.	• Fifteen (15) seconds have **not** elapsed since one of the events that trigger Summary Report to record have occurred. Wait fifteen (15) seconds and try again.

Pacer (Pacer Version Only)

Symptom	Recommended Action
14. "CHECK PADS" message.	• Ensure MFE Pads are connected to Multi-Function cable. • Ensure electrode gel is not dry. Replace MFE Pads if necessary. • Ensure good electrode-to-patient contact. • Check integrity of Multi-Function cable by plugging into test connector. "CHECK PADS" should disappear.
15. No stimulus marker (⎍) present on the ECG trace.	• Ensure unit is in **PACER** mode. • Ensure **PACER RATE** (ppm) is set greater than patient heart rate.
16. No ventricular capture beat after stimulus marker on ECG display.	• Check patient's pulse. • Increase output current. • Ensure MFE Pads are making good contact with the patient. • Select different ECG Lead configuration. • Review MFE Pad placement.
17. Patient on "Standby" pacing gets paced intermittently.	• Ensure proper ECG electrode connection and placement. If ECG lead wire comes off, pacer will automatically pace asynchronously. • Check ECG cable for damage. • Patient R-to-R interval varying. Pace rate close to patient rate. • Verify rate is set appropriately
18. Heart rate display reads 0 with proper pacing capture displayed on ECG trace.	• Check patient's pulse. • Select different ECG Lead configuration.
19. Bedside/Central Station/Telemetry ECG display becomes erratic when pacing.	• Patient monitor ECG inputs overloaded by pacer signals. ECG can only be monitored by the device while pacing.

Defibrillator

Symptom	Recommended Action
20. Excessive artifact when using paddles as ECG source.	• Ensure “PADDLES” is selected. • Firmly press paddles against patient skin. • Use gel on paddles. • Clean paddle surface. • Check and clean between adult and pediatric shoe. • Check cable for damage. • Use ECG electrodes.
21. Defibrillator will not charge (energy level does not increment on display).	• Check **SHOCK** button(s) on paddles or front panel are not stuck on. • Charge the battery pack.
22. Charge time to 360 J exceeds 10 seconds.	• Typical in a low battery condition (up to 20 seconds) • Change battery pack. • Plug device into AC power. • Install fully charged battery pack. • Install new fully charged battery pack
23. Energy does not discharge when the **SHOCK** button(s) is pressed.	• Sixty (60) seconds have elapsed in manual mode, since initial charge ready. Energy was internally discharged. • Fifteen (15) seconds have elapsed in automatic mode, since initial charge ready. Energy was internally discharged. • Device is in “SYNC” mode and no QRS complex is detected. • Energy internally discharged because energy selection was changed during charge or after the device was ready. • Unit not completely charged when **SHOCK** buttons were pressed. Wait for “DEFIB XXXJ READY” message and ready tone. • Press and hold **SHOCK** button(s) until energy is delivered to the patient.
24. Unable to **SHOCK** when in “SYNC” mode.	• Ensure “SYNC XXXJ SEL” is displayed on monitor. • Check for “SYNC” marker (arrow “” above R wave). If not present, change ECG size, lead selection, or electrode placement. • Press and hold **SHOCK** button(s) until energy is delivered to the patient. • Alter ECG electrode placement. • Make sure ECG signals are displayed.

Symptom	Recommended Action
25. No apparent energy delivery to patient.	• Under certain circumstances, some patients will not "twitch" when energy is delivered. • Perform defibrillator self test as described in **GENERAL MAINTENANCE** Section. • Check for "CHECK PADS" and "POOR PAD CONTACT" messages alternating on the monitor. • If Multi-Function Electrodes are used, ensure proper placement and contact.
26. "CHECK PADS" message.	• Verify proper Multi-Function Cable / MFE Pad connection by disconnecting and reconnecting the Mult-Function cable and MFE Pads. • Ensure proper contact of Multi-Function Pads and that the patient does not have excessive hair beneath the electrodes. • If message persists, disconnect Multi-Function cable from MFE Pads and plug cable into test connector. "CHECK PADS" should change to "DEFIB PAD SHORT" (Manual Mode Only). • If test fails, try using paddles to defibrillate.
27. "USE PADS" message.	• ECG Analysis will only operate when MFE pads are attached to the patient. • Disconnect paddle and connect MFE Pads for use in Semi-automatic defibrillation. • Activate manual mode to use Paddles
28. "NOISY ECG" "RETRY ANALYSIS" message	• Check for proper application and adhesion of Multi-Function Electrodes. • Check to make sure that nobody is touching the patient and that the patient is motionless.
29. "ECG TOO LARGE" "RETRY ANALYSIS" message.	• Press **ANALYZE** button again to begin analysis.
30. No "TEST OK" message when performing a defibrillator self-test.	• Check to make sure unit is set to 30 Joules. • If testing with Multi-Function Cable, make sure that cable is firmly inserted into test connector. • If testing with paddles, make sure to press the paddles firmly against the sides of the unit while discharging.
31. "DEFIB MAINT. REQUIRED" message.	• Contact ZOLL Technical Service Department.

AC Charger

Symptom	Recommended Action
32. The green and orange-yellow CHARGER ON indicators are alternately illuminating.	• Verify battery is installed. • Turn unit **ON** to identify the fault condition. • Replace battery pack with a fully charged battery pack. • If problem persists, replace battery pack, unplug device from AC mains and plug device back into AC mains.
33. “LOW BATTERY” message appears on monitor when unit is plugged into AC mains.	• Replace battery pack with a fully charged battery pack. • Unplug device from AC mains and plug device back into AC mains. • Verify AC mains is working properly.
34. None of the CHARGER ON indicators are illuminated when the device is plugged into AC mains.	• Unplug device from AC mains and plug device back into AC mains. • Verify AC mains is working properly.

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APPENDIX A
SPECIFICATIONS

General

Size	6.8 in. high X 10.3 in. wide X 8.2 in. deep 17.3 cm high X 26.2 cm wide X 20.8 cm -deep
Weight	11.5 lbs (5.23 kg) with Multi-Function Cable and battery; 13.5 lbs (6.14 kg) with paddles
Power	Sealed lead acid battery pack; 5 cells, 2V/cell (wired in series)
AC Power	100-120 ~ 50/60 Hz, 220-240 ~ 50 Hz, 220 VA
DC Input (Optional)	10-29 V. 130 W
Device Classification	Class I and internally powered per IEC 601-1. Class II and internally powered per IE 601-1. (DC Input ONLY).
Design Standards	Meets or exceeds UL 2601, AAMI SD-39, AAMI DF-2, IEC 601-2-4, IEC 601-2-25, and IEC 601-2-27.
Patient Safety	All patient connections are electrically isolated.
Environmental	Operating Temperature: 0 °C to 55 °C. **Note:** The M Series device may not perform to specifications when stored at the upper or lower extreme limits of storage temperature and immediately put into use. Storage and Shipping Temperature: -20° to 60°C Humidity: 5 to 95% relative humidity, non-condensing Vibration: Mil Std 810E, Minimum Integrity Test Shock: IEC 68-2-27, 50g 6mS half sine Operating Pressure: 594 to 1060 mBar Material Ingress: IEC 529, IP23 Electromagnetic Compatibility (EMC): CISPR 11 Class B - Radiated and Conducted Emissions Electromagnetic Immunity: AAMI DF-2: IEC 1000-4-3 to 20 V/m Electrostatic Discharge: AAMI DF-2: IEC 1000-4-2 Conducted Susceptibility: IEC 1000-4-4, 1000-4-5, 1000-4-6

Pacemaker (Pacer Version Only)

Type	VVI demand; asynchronous (fixed rate) when used without ECG leads or in ASYNC pacing mode.
Pulse Type	Rectilinear, constant current.
Pulse Shape and Duration	Rectilinear, 40 milliseconds ±2 milliseconds
Pulse Amplitude	Variable 0 mA to 140 mA ±5% or 5 mA, whichever is greater. Digitally displayed on the monitor (increments or decrements by a value of 2 mA).
Pacing Rate	Variable from 30 ppm to 180 ppm ±1.5% (increments or decrements by a value of 2 ppm).
Output protection	Fully defibrillator protected and isolated
Multi-Function Electrode (MFE) Pads	Specifically designed adult anterior/posterior pre-gelled ZOLL MFE Pads, and Multi-Function Stat•Padz packaged in pairs.

Defibrillator

Waveform	Dampened sinusoid.
Energy Selection	Selectable at 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 30, 50, 75, 100, 150, 200, 300, 360 J (Delivered into 50 Ω load). Selected using controls on sternum paddles or unit front panel.
Charge Time	Less than 7 seconds with a new fully charged battery (first 15 charges to 360 joules). Depleted batteries will result in a longer defibrillator charge time.
Energy Display	Monitor display indicates both selected and delivered energy.
Synchronized Mode	Synchronizes defibrillator pulse to patient's R-wave. 'SYNC" message displayed on monitor. Marker on display and recorder paper identifies R-wave discharge point.
Charge Controls	Control on apex paddle and on device front panel.
Paddles	Standard anterior/posterior adult and pediatric. Adult paddles slide off to expose pediatric paddles.
Multi-Function Electrode (MFE) Pads	Specifically designed adult anterior/posterior pre-gelled ZOLL MFE Pads, and Multi-Function Stat•Padz packaged in pairs.
Built-in Defibrillator Tester	Provides verification of the defibrillator charging and discharging without removing paddles from storage wells, or verification of unit configured with Multi-Function Cable.
Defibrillation Advisory	Evaluates electrode connection and patient ECG to determine if defibrillation is required. Shockable Rhythms: Ventricular fibrillation with amplitude > 100 μV and wide complex Ventricular tachycardia with rates greater than 150 bpm. Refer to the ECG Analysis Algorithm Accuracy section for sensitivity and specificity performance.
Multi-Function Electrode Impedance Measurement Accuracy	0 ohms - 250 ohms ±10% or 5 ohms, whichever is greater.

ECG Monitoring

Patient Connection	3-lead ECG cable, 5-lead ECG cable, paddles or MFE Pads. Selectable by front panel switch.
Input Protection	Fully defibrillator protected. Special circuit prevents distortion of ECG by pacer pulse. (Pacer version only).
Implanted Pacemaker Spike Display	Dedicated circuitry detects most implanted pacemaker spikes and provides standard display marker of spike on ECG trace.
Bandwidth	0.5 Hz - 21 Hz (-3 dB) standard/0.05 Hz - 150 Hz Diagnostic 0.5 Hz - 27 Hz and 1 Hz - 21 Hz user-configurable
Lead Selection	Displayed on monitor
ECG Size	0.5, 1, 1.5, 2, 3 cm/mV - display on monitor
Heart Rate	Digital display 0 bpm - 300 bpm ±5%
Heart Rate Alarm	On/Off displayed on monitor. User-selectable, Tachycardia 60 bpm - 280 bpm, Bradycardia 20 bpm - 100 bpm
1 Volt ECG Out	1.0 Volt/cm of deflection on strip chart recorder. < 25 ms delay from patient ECG input.
Display Format	Non-fade moving bar display.

Display

Screen Type	High resolution, electoluminescent or liquid crystal display (LCD)
Screen Size	5.66 inches (14.4 cm) diagonally (EL Display)
Sweep Speed	25 mm/sec
Viewing Time	4 seconds
Messages	Erasing Report, Insert Card, Card Full, Replace Battery, Low Battery, Perform CPR, ECG Too Large, Noisy ECG, Retry Analysis, Check Patient, Analysis Halted, Press Analyze, No Shock Adv., Check Pulse, Shock Advised, Press Charge, Select Pads, Select ECG Leads, Select Defib Mode, VF Alarms Off, Disable Sync, Analysis Restarted, Check Pads, Poor Pad Contact, Defib Pad Short, Paddle Fault, ECG Lead Off, Use Paddle DIschg, Open Air Discharge, Cannot Charge, Release Shock, 50 J Max, Press Shock, Test OK, Test Fail, Pacer Disabled, Defib Disabled, Set Pace mA, Set Pace Rate, Check Recorder, Analyzing ECG.

Recorder

Paper	80 mm thermal (grid width) 90 mm (paper width)
Speed	25 mm/sec
Delay	6 seconds
Annotations	Time, date, defib energy, heat rate, pacer output (Pacer version only), QRS sync marker, ECG size, lead, alarm, defib test OK/Fail, analyze ECG, Pads off, analysis halted, noisy ECG, shock advised, no shock advised, ECG too large, an d diagnostic bandwidth.
Printing Method	High resolution, thermal array print head.
Print-out Modes	Manual or automatic — user-configurable.
On/Off Control	Front panel and paddle.
Automatic Function	15 second recording initiated by alarm activation or defibrillator discharge.

PCMCIA Card

Capacity	Standard series II flash card - 1 megabyte to 16 megabytes.
Audio Recording	Digital compressed audio data.

Battery Packs

	PD 4410	**XL Battery**
Type	Rechargeable, sealed lead acid	Rechargeable, sealed lead acid
Weight	1 kg (2.2 lbs)	1.7 kg (3.7 lbs)
Voltage	2V/cell; 5 cells wired in series	2V/cell; 5 cells wired in series
Recharge Time	4 hours or less with integral charger	7.2 hours or less with integral charger
Operating Time	For a new, fully charged battery pack at 20 °C: 35 defibrillator discharges at maximum energy (360 J), or 2.75 hours of continuous ECG monitoring, or 2.25 hours of continuous ECG monitoring/pacing at 60 mA, 80 beats/min.	For a new, fully charged battery pack at 20 °C: 60 defibrillator discharges at maximum energy (360 J), or 4 hours of continuous ECG monitoring, or 3.25 hours of continuous ECG monitoring/pacing at 60 mA, 80 beats/min.

Note: Each monitoring option added to the **M Series** device decreases the Operating Time that can be obtained from a fully charged battery. Refer to the individual Option Insert for the Operating Run Time specific to your device. For further details specific to your device, contact the ZOLL Technical Service Department.

Low Battery Indicator	Message displayed on monitor and 2-beep low battery tone sounds once a minute until just before shutdown, when it will beep twice every 2 seconds. The time from display of the "LOW BATTERY" or "REPLACE BATTERY" message until the instrument shuts down will vary depending upon the battery age and condition.

APPENDIX B
MEDICAL REPORT CAPABILITY

The unit's medical report capability automatically records incident information for subsequent review and archiving. Data is stored on a removable PCMCIA type II data card (memory card) for uploading to a properly equipped personal computer.

The medical report capability begins recording when the unit is turned on and continues until the unit is turned off. Patient ECG, unit status, date, time and control settings are recorded. Audio recording using a microphone located on the front of the unit is optional.

Data recorded during an incident is retained on the memory card until erased. Shutting the unit off with the memory card installed or removing the memory card from the unit will not erase the data.

PCMCIA Data Card

The memory card is a self-contained electronic storage unit similar to a floppy disk.

- Do not subject the card to extreme temperatures.
- Do not immerse the card in liquids.
- Do not place the card near magnetic objects.
- Do not place heavy objects on the card.
- Protect the connector located on the card from physical damage.

Contact ZOLL Technical Service Department for the current list of supported PCMCIA cards.

Up to two hours of incident data (ECG and unit status) or up to 38 minutes of incident data and simultaneous audio recording can be stored on one 4-megabyte memory card. ZOLL recommends that a spare memory card be kept with the unit at all times and that the memory card be changed after each incident.

Installing the PCMCIA Data Card

Check that there is no physical damage to the connector edge and that the connector edge is clean and free of dirt and debris. Insert the memory card into the slot located on the bottom of the unit. The label side should be up. Slide the card into the unit until it is firmly seated in the card slot.

To remove the card, press the release button and pull the card out of the unit. If the memory card is removed while the unit is on, the unit will still operate properly but no event information will be recorded.

Erasing A Memory Card

If the unit is configured to allow card erasure, memory cards can be erased. See the M Series Configuration Guide for further details on the Allow Card Erase configuration option.

To erase card memory:

1. Turn off the unit. The unit must remain turned off for at least 10 seconds.
2. Hold down the left-most softkey for 4 seconds while turning selector switch to MONITOR (ON for AED). The M Series should now be in the System Utilities mode.
3. Press the Erase Cards softkey.
4. Press the Next Item softkey to select YES.
5. Press the Enter softkey.

   The M Series unit erases the card and displays the Erasing Card message. A progress bar displays while erasing the card. When the card is completely erased, the Card Erased message displays.

   If the No Card Inserted message displays, insert a PCMCIA into the card slot. If the Card Operation Failed message displays, the card is either write-protected or damaged.
6. Do either:

- Press the Enter softkey to erase another card.
- Press the Next Item softkey and then the Enter softkey to exit.

When finished erasing memory cards, the M Series can be returned to normal use by powering the unit off and then back on.

Warning Messages

If configured, the following messages are displayed to prompt the user to check the PCMCIA card.

CARD FULL

The PCMCIA Data Card is full. No more data will be stored on the card but the unit will continue to operate. This prompt is only given when the unit is not analyzing or charging. Insert another card or print event data on strip chart recorder.

INSERT CARD

The memory card is not installed or not seated properly in the unit.

REPLACE CARD

The wrong card type is installed, the card is defective, or an Erase Card operation was interrupted. The unit will operate, but no data will be stored. Erasing the card may allow return to normal data storage operation.

NO AUDIO RECORDING

(Only available with voice recording option.)

The PCMCIA Data Card has been removed from the M Series while the unit is turned on. The unit will not record event or audio information.

Transferring Data to a PC with a PCMCIA Data Card Reader

ZOLL Data Control for Windows® must be installed on the PC to access any information stored on PCMCIA cards.

Remove the data card from the unit. Insert the card into the PCMCIA data card reader on the PC.

Refer to the ZOLL Data Control for Windows® Reference Manual for instructions on information retrieval and PC equipment requirements.

Uploading Data to a PC via A Serial Link

ZOLL Data Control for Windows® software must be installed on the PC to access any data uploaded from the PCMCIA data card inserted in the M Series.

Connect the RS-232 cable (ZOLL PN 9500-0605-01) to the RS 232/ECG port on the back of the **M Series** and to the PC serial port. If necessary, use a 9-pin to 25-pin adapter on the PC.

Data may be uploaded from the **M Series** to the PC using ZOLL Data Control for Windows® software as the data communications package. (See the ZOLL Data Control for Windows® Reference Manual for details.) A utility software package such as HyperTerminal may also be used.

The correct communications settings are:

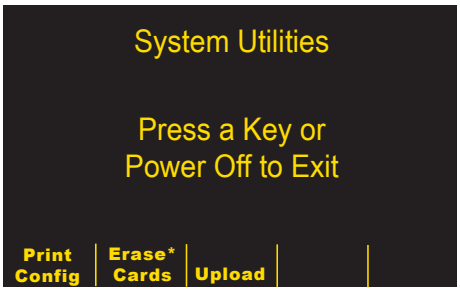
Bits per second*	115 200 bps (default) You can also use 9600 bps or 38 400 bps
Data bits	8
Parity	None
Stop bits	1
Flow control	None

*Bits per second must be the same as the baud rate setting of the **M Series** unit. See the M Series Configuration Guide for instructions on how to configure the **M Series** baud rate.

Note that upload times vary. For example, a 2 MB card containing 30 minutes of recorded incident and audio data may take up to four minutes to upload at a baud rate of 115 200 bps. At a baud rate of 9600 bps, this same upload may take up to 40 minutes.

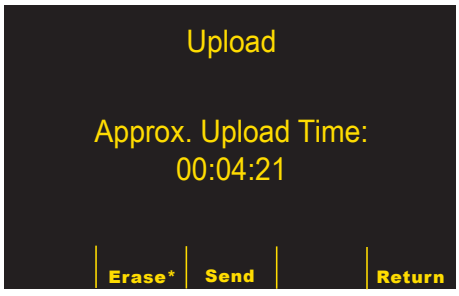
To transfer data:

1. Make sure the unit is turned off for at least 10 seconds. Press the left-most softkey while rotating the rotary switch to the ON or Monitor position. Wait 4 seconds. The System Utilities screen displays.



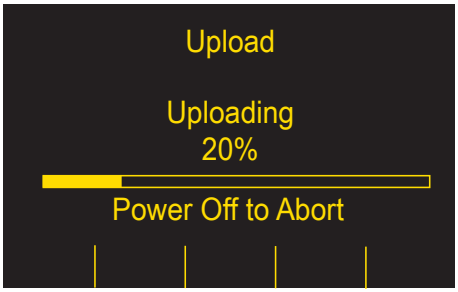
Note: Softkeys and messages denoted with an asterisk (*) are displayed only if unit is configured to allow card erase.

2. Insert the data card to be uploaded into the bottom PC card slot of the unit.
3. Press the Upload softkey. The main Upload screen displays.

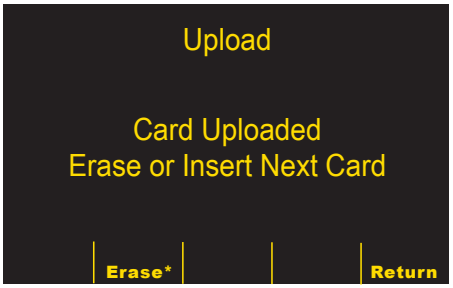


4. Activate the communication software on the receiving PC. If not done already, prepare the host system (PC) to receive a data file by entering the communications settings as shown on the previous page.
5. Press the Send softkey. Uploading begins in about one second. The Upload screen displays a progress bar that indicates the percentage of data transferred to the PC. To stop data transmission, move the unit's rotary switch to OFF.

Note: Card data must be re-transmitted if the unit is shut off before all data stored in the card has been transmitted.



6. Following a successful transmission, the unit displays the Card Uploaded screen. To upload another card, remove the current card, insert a new card, and press the Send softkey again. (The Send softkey appears when the new card is inserted.)



After transmission, file names created by the communications program on your PC have the following format:

ZLssssssss_YYYYMMDD_HHMMSSL.crd

where:

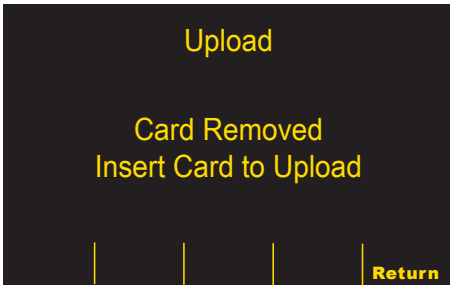
ssssssss	=	Unit serial number
YYYYMMDD	=	Year, month and day of transmission
HHMMSS	=	Hour, minute, and second of transmission
L	=	A unique identifier associated with the file that increments sequentially through the alphabet (e.g., A, B, C, etc.)

Example: ZL12345678_20010825_183005A.crd
Unit 12345678 August 25, 2001, 6:30:05 PM.

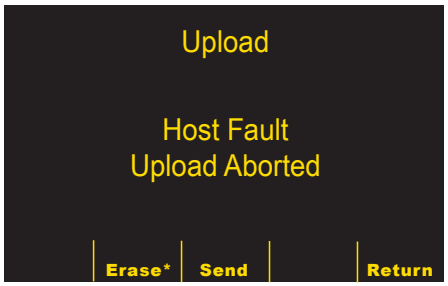
Troubleshooting

(See Display Message table below for additional Troubleshooting information.)

If the card is not inserted properly into the PCMCIA card slot when data transmission is attempted, the following screen displays. Check the insertion of the card. The card may need to be reinserted so that it is seated properly.



If during transmission, the PC halts its reception of data, a “Host Fault” message appears and the upload stops.



Display Messages

Message	Reason/Action
Card Removed	Card was removed from PCMCIA slot or is not seated properly. Reinsert card.
Empty Card	Empty data card inserted into PCMCIA slot or card was erased. Record data on card before transmission or insert different card.
Not a Data Card	Wrong type of card. Insert a data card.
Host Fault	Transmission was stopped because PC detected an error or user cancelled transmission via the PC communication program. Check the communications package or utility running on the PC for the source o the error.
Serial Fault	The cable is not connected, the PC host is not detected, or a transmission error occurred. Check and secure the RS 232 cable at the back of the unit or the PC. Check the settings on the communication package or HyperTerminal.
Card Uploaded	Upload successful
Card Previously Uploaded	User inserted a valid data card that was already uploaded successfully. Data on card not erased. Use a different data card, erase the data on the card you are using, or resend the data again.